



M.C.E. Society's

**M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES &
RESEARCH CENTRE, PUNE**

Recognized by Dental Council of India & Affiliated to M.U.H.S. Nashik

2390-B, K.B. Hidayatullah Road, Azam Campus, Camp, Pune-411001 (Maharashtra)

Tel: 91-20-26430959, 26430960, 26430961

Fax No. 91-20-26430962

E-mail: info@mardentalcollege.org

Website: www.mardentalcollege.org

Name of the Partnering Agency/Institution: Dr D. Y Patil Dental college and Hospital

Number of Participants : 4 faculty

Duration :3 years (17th Feb 2023 – 16th Feb 2026)

A collaborative research is being carried out at Dr D.Y Patil Dental college and Hospital titled “ **The possible association of Salivary pH, flow rate, viscosity, buffering capacity and MMP20 in the etiology of Molar Incisor Hypomineralization: A Clinical Study** ” The synopsis of the aforementioned study has been drafted and has been approved by the IEC. Two researchers from the Department of Pedodontics and Preventive Dentistry, and one from the Department of Biochemistry are involved, the names of whom are as follows.

1. Dr. Rooposhi Saha
2. Dr Nilesh Rathi
3. Dr Vanishree B.K
4. Dr Namrata Khanna
5. Dr Yusuf Chunawala



PRINCIPAL
**M. A. RANGOONWALA COLLEGE OF DENTAL
SCIENCES & RESEARCH CENTRE, PUNE**

**M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH
CENTER, PUNE**

DEPARTMENT OF PEDODONTICS & PREVENTIVE DENTISTRY

In association with

Dr. D. Y. PATIL DENTAL COLLEGE & HOSPITAL, PUNE

SYNOPSIS

**The possible association of salivary pH, flow rate, viscosity buffering capacity and
MMP20 in the etiology of Molar Incisor Hypomineratization: A Clinical study**



Topic of Synopsis

DR. ROOPOSHI SAHA

The possible association of salivary pH, flow rate, viscosity, buffering capacity and MMP20 in the etiology of Molar Incisor Hypomineratization: A Clinical study



Topic of synopsis

Submitted to

The

MAHARASHTRA UNIVERSITY OF HEALTH SCIENCE

**The possible association of salivary pH, flow rate, viscosity, buffering capacity and
MMP20 in the etiology of Molar Incisor Hypomineratization: A Clinical study**



1.	TITLE	The possible association of salivary pH, flow rate, viscosity, buffering capacity and MMP20 in the etiology of Molar Incisor Hypomineralization: A Clinical study
2.	INTRODUCTION	<p>Molar Incisor Hypomineralization (MIH) is a novel disease that has come up in this century in the field of pediatric dentistry¹. MIH mostly affects the enamel of the first permanent molars, which help us to grind food², it might or might not involve the permanent incisors, responsible for biting and cutting of dietary substrates and also play a crucial role in phonetics³. 13.5-14.2% overall average has been reported by recent systematic reviews, which is constantly increasing⁴.</p> <p>In MIH, teeth have morphologically normal enamel however it is deficient in its structure⁵. Affected enamel is more porous, softened, and shows white, yellow, or brownish opacities; this might be due to the decrease in the quantity and quality of minerals⁶. Therefore, the defective tooth becomes more fragile with increased susceptibility to caries aggravated sensitivity issues⁶; leading to challenging dental procedures⁵. There is no definitive treatment for this condition⁷, but only palliative treatment can be provided to prolong the vitality of the tooth, and to improve the oral health-related quality of life of the children.</p> <p>According to the enamel hypomineralization rate, MIH was classified into different degrees of severity. White, yellow, or brown demarcated opacities, were assigned as a mild degree of MIH; and post-eruptive enamel breakdown jointly with opacities, carious lesions, or complex restorations disconnected to caries pattern, was defined as severe⁸.</p> <p>Systemic health disturbances that occur during the permanent teeth mineralization period have been suggested as to play a possible role in the etiology of MIH⁹. Among these disorders, early childhood diseases, i.e. asthma¹⁰, frequent use of antibiotics¹¹, as well as genetic influences¹² (considering that enamel-forming cells are genetically controlled) should be highlighted. In summary, over the last decade, more than 30 systemic etiological hypotheses have been identified; some are well established, and others are more contemporary¹³.</p>



It makes sense that the protein makeup of saliva is connected to illness, given that saliva regulates enamel remineralization and that MIH is linked to increased saliva flow rate. It has been observed that the flow rates, viscosity, pH, and acid buffering ability of MIH patients' saliva and the protein composition of MIH saliva may display recognizable alterations that either induce or exacerbate the clinical signs of this illness¹⁴.

Outstandingly, saliva is a body fluid with complex composition, capable of playing a variety of roles connected with oral and systemic health¹⁵. It contains bicarbonate ions, which are responsible for the buffering capacity, neutralizing organic acids produced by bacterial food substrates fermentation¹⁶. Hence, teeth demineralization could be minimized. Several saliva components or proteins can interact with pathogenic bacteria and may be involved in the protection of dental tissues, such as statins, mucins, lactoferrin, defensins, and peroxidases¹⁷.

Although saliva contains numerous peptides, many of them have not yet been fully characterized¹⁷. With scientific advances, state-of-the-art techniques, such as mass spectrometry analysis, for example, have provided a better understanding of the causes of oral pathologies, identifying biomarkers at a molecular level¹⁸.

Since inconclusive literature with contrasting results exists, this study will be carried out to compare and establish an association between MIH, MMP20, salivary pH, flow rate, viscosity and buffering capacity in children.

		<p>It makes sense that the protein makeup of saliva is connected to illness, given that saliva regulates enamel remineralization and that MIH is linked to increased saliva flow rate. It has been observed that the flow rates, viscosity, pH, and acid buffering ability of MIH patients' saliva and the protein composition of MIH saliva may display recognizable alterations that either induce or exacerbate the clinical signs of this illness¹⁴.</p> <p>Outstandingly, saliva is a body fluid with complex composition, capable of playing a variety of roles connected with oral and systemic health¹⁵. It contains bicarbonate ions, which are responsible for the buffering capacity, neutralizing organic acids produced by bacterial food substrates fermentation¹⁶. Hence, teeth demineralization could be minimized. Several saliva components or proteins can interact with pathogenic bacteria and may be involved in the protection of dental tissues, such as statins, mucins, lactoferrin, defensins, and peroxidases¹⁷.</p> <p>Although saliva contains numerous peptides, many of them have not yet been fully characterized¹⁷. With scientific advances, state-of-the-art techniques, such as mass spectrometry analysis, for example, have provided a better understanding of the causes of oral pathologies, identifying biomarkers at a molecular level¹⁸.</p> <p>Since inconclusive literature with contrasting results exists, this study will be carried out to compare and establish an association between MIH, MMP20, salivary pH, flow rate, viscosity and buffering capacity in children.</p>
3.1	PRIMARY RESEARCH QUESTION	Is there any correlation between occurrence of MIH and salivary MMP20 of a child?
3.2	OTHER RESEARCH QUESTION 1	Is there any correlation between occurrence of MIH and salivary pH, flow rate, viscosity and buffering capacity in a child?
3.3	OTHER RESEARCH QUESTION 2	Not applicable
4.1	Null HYPOTHESIS	There is no difference in the occurrence of MIH and salivary MMP20 of a child.
4.2	Alternative HYPOTHESIS 1	There is difference in the occurrence of MIH and salivary pH, flow rate, viscosity & buffering capacity of a child.



4.3	OTHER HYPOTHESIS 2	Not applicable
5.	REVIEW OF LITERATURE	<ol style="list-style-type: none"> 1. Jalevik B. 2001 A sample of 516 Swedish 8-year-old kids had a lot of hypomineralization in their permanent first teeth. Among 95 kids (18.4%), there was at least one molar with distinct opacity. The incisors usually showed concurrent opacities. The afflicted children had 3.2 (SD 1.8) hypomineralized teeth on average, 2.4 of which were first molars. A total of 6% of the kids had severe problems, 5% had moderate deficiencies, and 7% had teeth that were just minimally hypomineralized. More than one tooth was impacted in 15% of cases which suggests systemic cause. Throughout the first year of life, the afflicted children, particularly the males, were said to have experienced increased health issues, including asthma (albeit there were only 4 cases). Children with and without enamel abnormalities had comparable breastfeeding histories.¹⁹ 2. Weerheijm K 2003. Molar Incisor Hypomineralisation (MIH) is defined as hypomineralisation of systemic origin of one to four permanent first molar frequently associated with affected incisors. MIH molars are fragile and caries can develop very easily in those molars. Although MIH molars are well known by paediatric dentists and their occurrence is related in severe cases to major clinical problems, only limited data of the size of the problem are available. The prevalence of MIH ranges in the literature from about 3.6 to 25% and seems to differ in certain regions and birth cohorts. Unfortunately more complete comparable valid data are lacking at the moment. It seems that several aetiological factors can cause the enamel defects and that their occurrence is child related. For children with repeated illnesses in the first years after birth and children with opacities on erupted molars or incisors it seems useful to increase the frequency of dental check-ups during the period of erupting first permanent molars⁶. 3. Hussein A.S. 2015 Molar-Incisor First permanent molars and commonly permanent incisors are affected by the condition of hypomineralized enamel of systemic origin known as hypomineralization (MIH). It is seen as a worldwide



issue, and information from Malaysia and other South-East Asian nations is limited. As a result, the purpose of this study was to examine the prevalence and severity of MIH in a group of kids aged 7 to 12 who were enrolled in a paediatric dentistry clinic at the Faculty of Dentistry, Universiti Teknologi MARA (UTM) Malaysia.²⁰

4. Almualllem, 2018 Recent data indicates that molar-incisor hypomineralisation (MIH) is a frequently – encountered dental condition worldwide. The condition could be associated with dental complications that might affect patients' quality of life as well as create treatment challenges to dentists. The affected teeth are more prone to caries and post-eruptive enamel breakdown, therefore, it is believed that this condition might be responsible for a substantial proportion of childhood caries since the condition has high prevalence. MIH is common as such it should be diagnosed and managed in primary care wherever possible. Early diagnosis can lead to more effective and conservative management²¹
5. Bekes k. 2020 Uncertain pathophysiology characterises the endemic paediatric condition known as molar incisor hypomineralization (MIH). We proposed that the protein content of saliva is related to illness because saliva regulates enamel remineralization and MIH is connected to increased saliva flow rates. We enrolled 5 kids between the ages of 6 and 14 with MIH demonstrating at least one hypersensitive molar and 5 kids without hypomineralization to test the hypothesis. According to this study, MIH patients' salivary proteome composition was altered, revealing a catabolic environment associated to inflammation.²²
6. Zilberman 2020. Enamel formation is a highly coordinated process. The enamel protein matrix, secreted by the ameloblasts, contains three main proteins: amelogenin, enamelin and ameloblastin. These proteins are specific to enamel and are degraded by specific proteases, MMP20 and KLK4. Human mutations in these genes coding for the enamel proteinases cause variable degrees of hypomineralization. In MIH permanent molars the mineral content is very low and the protein content may reach 30-40% in volume. We should look at the function of MMP20 and KLK4 during the first two years of life in order to understand the findings in MIH²³



7. Aline leite de Farias 2022 to evaluate the existence and severity of the relationship between MIH and enamel hypomineralization in the second permanent molars. When first permanent molars badly impacted by molar incisor hypomineralization are being considered for extraction, the second permanent molar is crucial (MIH). The first and second permanent molars are most affected by enamel hypomineralization. Patients with severe MIH in the first permanent molars are more likely to have mild second permanent molar abnormalities. Dental caries experience was increased when enamel hypomineralization was present.²⁴
8. Toledo S et al, 2022 Saliva is a rich-bodily fluid with recognized clinical diagnosis roles and this research aimed at investigating if there is any change in the salivary proteome signatures of MIH children with distinct degrees of severity. Fifty schoolers (6–10 years) were equally assigned into the following groups: G1 (Control group - Healthy teeth), G2 (Mild MIH with white/creamy opacity and free of caries), G3 (Mild MIH with yellow/brown opacity and free of caries), G4 (Severe MIH with white/creamy, yellow/brown opacities including post-eruptive fracture and free of caries), G5 (Severe MIH with white/creamy, yellow/brown opacities, post-eruptive fracture, and caries). Unstimulated saliva samples were collected and later explored using mass spectrometry analysis. In total, 6,471 proteins were found, 5,073 exclusively from MIH children, and 778 overlapping among the different degrees of the disturb. The Biological Pathways displayed distinct patterns among the groups being different according to the degrees of MIH. Gene- Odontology difference might not be verified regarding the biological processes and cellular components. Conversely, with respect to molecular function, alterations among groups were evident, with the presence of proteins that would contribute to MIH in children with the severe condition (i.e, calcium ion binding, microtubule binding, platelet-derived growth factor binding). In conclusion, the results of this study support important salivary proteomic changes in MIH children, according to distinct degrees of severity, reinforcing the interplay between the clinical characteristics and changes in the salivary proteome.



OPERATIONAL DEFINITIONS:

Molar incisor hypo mineralisation (MIH) is a common developmental dental condition that presents in childhood. Areas of poorly formed enamel affect one or more permanent molars and can cause opacities on the anterior teeth. MIH presents a variety of challenges for the dental team as well as functional and social impacts for affected children.

MMP20 (Enamelysin) has been shown to be expressed by secretory stage ameloblasts. It is the only proteinase present in the enamel matrix during the secretory stage. The main function of MMP20 is to cleave the most abundant enamel matrix protein, amelogenin. It is also likely responsible for generating an enamelin cleavage product. MMP20 will also cleave the KLK4 propeptide to produce catalytically active KLK4. Human MMP20 is expressed from a gene on chromosome 11q22-q23. Seven different human MMP20 mutations are known to cause autosomal recessive hypomaturation hypoplastic-hypomaturation Amelogenesis Imperfecta (AI). The teeth are normal in appearance but the enamel layer does not contrast well with dentin on radiographs and the enamel tends to chip away. The lack of functional MMP20 in mammalian species without enamel (baleen whales), demonstrate that MMP20 is essential for enamel formation but is not essential for any other biological function.

APPROPRIATE METHODS OF MEASUREMENT:

Assessment of MIH

The diagnosis of MIH will be made by visual inspection, using headset light, gauze (after cleaning and drying teeth) and clinical mirror. MIH detection will be performed according to the European Academy of Paediatric Dentistry (EAPD)¹ criteria.

Saliva samples collection and preparation

Unstimulated saliva samples will be obtained from all participants. The study participants will be told to skip all oral hygiene treatments, chewing gum, and analgesics/relievers for 8 hours, as well as to skip eating, drinking, and brushing for 1 hour before examination. Salivette will be used to collect saliva (Sarstedt, Germany). Subjects



asked to spit and samples were stored in Oragen DNA self-collection kits at room temperature until been processed. No centrifugation was performed in the saliva samples. After centrifuging the samples at 4 °C for 10 min. at 10,000 rpm, they will be kept at 20 °C until they are used. Saliva will be examined for pH and buffering capacity

APPROPRIATE STUDY INSTRUMENTS:

- a) Mouth mirror
- b) Salivette
- c) Centrifuge machine.
- d) Measuring cup
- e) pH meter
- f) Viscometer
- g) Elisa reader.

STEPS IN THE CONDUCT OF STUDY

Subjects will be divided into two groups, Group I and Group II. Group I will consist of subjects with MIH. Group II will consist of subjects without MIH.

The subjects will then be scrutinized for MIH, salivary MMP20, pH, flow rate, viscosity & buffering capacity using appropriate methods.

Methods of Data collection: The data will be collected by subject examination fulfilling the inclusion criteria, in subject information sheet.

Appropriate data management and analysis procedure:

Statistical analysis will be performed using Statistical Product and Service Solutions (SPSS) version 21 for Windows (SPSS Inc, Chicago, IL).

Descriptive quantitative data will be expressed in mean and standard deviation respectively.

Descriptive qualitative data will be expressed in percentage.

Data normality will be checked by using Shapiro – Wilk test.



Confidence interval is set at 95% and probability of alpha error (level of significance) set at 5%. Power of the study set at 80%.

Intergroup comparison between both groups in respect to quantitative study parameters will be done using unpaired t test (parametric)/Mann Whitney U test (non-parametric).

Intergroup comparison between both groups in respect to qualitative study parameters will be done using Chi square test.

Appropriate data analysis plan and methods: As mentioned above.

Additional points for Research in AYUSH: Not applicable

Additional points for RCT: Not applicable

Additional points for all Experimental Studies: Not applicable

8.

**REFERENCE
STYLE
(Vancouver)**

1. Weerheijm KL, Duggal M, Mejare I, Papagiannoulis L, Koch G, Martens J, Hallonsten AL. Judgement criteria for molar incisor hypomineralisation (MIH) in epidemiologic studies: a summary of the European meeting on MIH held in Athens, 2003. *Eur J Paediatr Dent.* 2003b Sep;4(3):110-3. PMID: 14529329.
2. Gaiser S, Deyhle H, Bunk O, White SN, Müller B. Understanding nano-anatomy of healthy and carious human teeth: a prerequisite for nanodentistry. *Biointerphases.* 2012 Dec;7(1-4):4. doi: 10.1007/s13758-011-0004-8. Epub 2012 Feb 9. PMID: 22589047.
3. Abdalla R. Teaching dental anatomy & morphology: An updated clinical-digital-based learning module. *Eur J Dent Educ.* 2020 Nov;24(4):650-659. doi: 10.1111/eje.12552. Epub 2020 Jul 1. PMID: 32531077.
4. Lopes LB, Machado V, Mascarenhas P, Mendes JJ, Botelho J. The prevalence of molar-incisor hypomineralization: a systematic review and meta-analysis. *Rev Bras Odontol.* 2021 Nov 17;11(1):22405. doi: 10.1038/s41598-021-01541-7. PMID: 34789780; PMCID: MC8599453.
5. Taylor GD. Molar incisor hypomineralisation. *Evid Based Dent.* Mar;18(1):15-16. doi: 10.1038/sj.cbd.6401219. PMID: 28338027.



6. Weerheijm KL. Molar incisor hypomineralisation (MIH). *Eur J Paediatr Dent* 2003 Sep;4(3):114-20. PMID: 14529330
7. Mast P, Rodrigueztapia MT, Daeniker L, Krejci I. Understanding MIH definition, epidemiology, differential diagnosis and new treatment guidelines *Eur J Paediatr Dent*. 2013 Sep;14(3):204-8. PMID: 24295005.
8. Negre-Barber A, Montiel-Company JM, Catalá-Pizarro M, Almerich-Silla JM. Degree of severity of molar incisor hypomineralization and its relation to dental caries. *Sci Rep*. 2018 Jan 19;8(1):1248. doi: 10.1038/s41598-018-19821-0. PMID: 29352193; PMCID: PMC5775201.
9. Salem K, Aziz D, Asadi M. Prevalence and Predictors of Molar Incisor Hypomineralization (MIH) among Rural Children in Northern Iran. *Iran J Public Health*. 2016 Nov;45(11):1528-1530. PMID: 28032070; PMCID: PMC5182269
10. Rizzardi KF, da Silva Toledo E, Ferraz LFC, Darrieux M, Girardello R, de Lima Marson FA, Parisotto TM. Association between asthma and enamel defects in primary and young permanent teeth – A systematic review. *Pediatr Pulmonol*. 2022 Jan;57(1):26-37. doi: 10.1002/ppul.25737. Epub 2021 Nov 8. PMID: 34698451.
11. Ghanim A, Manton D, Mariño R, Morgan M, Bailey D. Prevalence of demarcated hypomineralisation defects in second primary molars in Iraqi children. *Int J Paediatr Dent*. 2013 Jan;23(1):48-55. doi: 10.1111/ij.1365263X.2012.01223.x. Epub 2012 Jan 25. PMID: 22276809.
12. Vieira AR, Kup E. On the Etiology of Molar-Incisor Hypomineralization. *Caries Res*. 2016; 50(2):166-9. doi: 10.1159/000445128. Epub 2016 Apr 26. PMID: 27111773.



13. Garot E, Rouas P, Somani C, Taylor GD, Wong F, Lygidakis NA. An update on the aetiological factors involved in molar incisor hypomineralisation (MIH): a systematic review and meta-analysis. *Eur Arch Paediatr Dent.* 2021 Feb;23(1):23-38. doi: 10.1007/s40368-021-00646-x. Epub 2021 Jun 24. PMID: 34164793.
14. Bekes K, Mitulović G, Meißner N, Resch U, Gruber R. Saliva proteomic patterns in patients with molar incisor hypomineralization. *Scientific reports.* 2020 Mar 5;10(1):1-1.
15. Khurshid Z, Zohaib S, Najeeb S, Zafar MS, Rehman R, Rehman IU. Advances in Proteomic Sciences in Dentistry. *Int J Mol Sci.* 2016 May 13;17(5):728. doi: 10.3390/ijms17050728. PMID: 27187379; PMCID: PMC4881550.
16. de Sousa ET, Lima-Holanda AT, Nobre-Dos-Santos M. Changes in the salivary electrolytic dynamic after sucrose exposure in children with Early Childhood Caries. *Sci Rep.* 2020 Mar 5;10(1):4146. doi: 10.1038/s41598-020-61128-8. PMID: 32139791; PMCID: PMC7057989.
17. Pappa E, Vougas K, Zoidakis J, Vastardis H. Proteomic advances in salivary diagnostics. *Biochim Biophys Acta Proteins Proteom.* 2020 Nov;1868(11):140494. doi: 10.1016/j.bbapap.2020.140494. Epub 2020 Jul 1. PMID: 32663525.
18. Vitorino R, Lobo MJ, Ferrer-Correira AJ, Dubin JR, Tomer KB, Domingues P, Amado FM. Identification of human whole saliva protein components using proteomics. *Proteomics.* 2004 Apr;4(4):1109-15. doi: 10.1002/pmic.200300611. PMID: 15048992.
19. Jälevik B, Klingberg G, Barregård L, Norén JG. The prevalence of demarcation opacities in permanent first molars in a group of Swedish children. *Acta Odontologica Scandinavica.* 2001 Jan 1;59(5):255-60.



20. Hussein AS, Ghanim AM, Abu-Hassan MI, Manton DJ. Knowledge management and perceived barriers to treatment of molar-incisor hypomineralisation in general dental practitioners and dental nurses in Malay. *European archives of paediatric dentistry*. 2014 Oct;15:301-7
21. Almualllem Z, Naudi-Busuttil A. Molar-incisor hypomineralization(MIH)-overview. *British Dental Journal*. 2018 Oct 12; 225(7):601-609.
22. Bekes K, Mitulović G, Meißner N, Resch U, Gruber R. Saliva proteomic patterns in patients with molar incisor hypomineralization. *Scientific reports*. 2020 May 5;10(1):1-1.
23. Zilbermam U. Amelogenesis and MIH-Role of MMP20 and KLK4. *Rom J Dent Med*. 2020, Vol XXIII; No 3-4; 193-203
24. Elora Silva Toledo, Karina Ferreira Rizzardi, Fabíola Galbiatti de Carvalho Marinês Nobre-dos-Santos, Juliana Mozer Sciani, Thaís Manzano Parisotto. Salivary Proteomic Patterns in Children Affected by Different Severity Degrees of Molar Incisor Hypomineralization. *Research Square*; DOI: <https://doi.org/10.21203/rs.3.rs-2309540/v1>



Appendix 'A'

Name of The P.G college	M.A.Rangoonwala College of Dental Science & Research Centre, Pune
Department	Pediatric and Preventive Dentistry
Name of the Principal investigator & college	Dr. Rooposhi Saha, Professor, M.A. Rangoonwala College of Dental Science & Research Centre, Pune

Through Proper Channel Only

To
The Registrar,
MUHS, Nashik-422004.

Subject: - Submission of Topic of Research project


Respected Sir,

I, Dr. Rooposhi Saha, Professor in Pediatric and Preventive dentistry, am submitting the Title of my research project as mention below along with names of my co investigators.

TITLE OF SYNOPSIS:

The possible association of salivary pH, flow rate, viscosity, buffering capacity and MMP20
in the etiology of Molar Incisor Hypomineratization: A Clinical study

Kindly accept and register my Title of research project.



Principal investigator
Dr Rooposhi Saha
Professor, Pedodontics & Preventive Dentistry

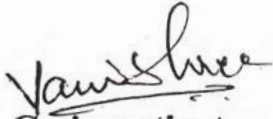




Co investigator

Dr Nilesh Rath

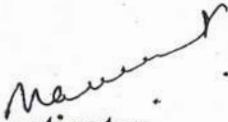
Prof. & Head, Pedodontics & Preventive Dentistry, DPU



Co investigator

Dr Vanishree B. K.

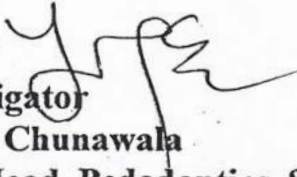
Reader, Pedodontics & Preventive Dentistry



Co investigator

Dr Namrata Khanna


Reader, Biochemistry



Co investigator

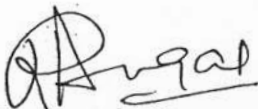
Dr Yusuf Chunawala

Prof. & Head, Pedodontics & Preventive Dentistry, MARDC



Dr. Yusuf Chunawala

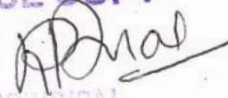
(Name and signature of HOD)



Dr. Ramandeep Duggal

(Signature and Seal of Dean of the college)

TRUE COPY



M. A. RAMCHANDANI, DEAN OF DENTAL
SCIENCE, MARDC, PUNE





ETHICS COMMITTEE OF M.C.E. SOCIETY

Azam Campus, Pune - 411 001. (INDIA)
Tel. : 91-020-26430959 Fax : 91-020-26430962
E-mail - dr.farha.mardc@gmail.com
Reg.No. - ECR/511/INST/MH/2014/RR-20

P.A. Inamdar
President

Dr. Farha Rizwan
Secretary

Dr. P. M. Bulakh
Chairman

Ref. No: MCES/EC/ 853/2023

Date: 14 SEP 23

ANNEXURE III

To,
Dr. Rooposhi Saha
Professor
Department of Pedodontics
M. A. Rangoonwala College of Dental Sciences and Research Centre,
Pune.

Dear Madam/Sir,

The Ethics Committee of the M.C.E.Society, Pune. reviewed the project entitled "The Possible Association of Salivary pH, Flow Rate, Viscosity, Buffering Capacity and MMP20 in the Etiology of Molar Incisor Hypominerization: A Clinical Study"

During its regular meeting held on 08th September 2023 attended by the E.C. members.

Kindly submit the following documents:-

1. C.V. of Principal Investigator
2. C.Vs of Co- Investigators
3. Marathi and Hindi translation of Consent form

The project has been

Approved

Approvable, subject to the amendments listed below


Disapproved for reasons listed below

Terminated for reason listed below

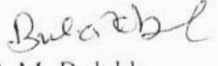
Subject to the PI providing the following:

- ❖ At least three months animal study report
- ❖ A six-monthly detailed report of the clinical trial/study ✓
- ❖ A written report of each serious or unexpected (as per the Investigator's Brochure) adverse event with regard to the study
- ❖ Not to make any. amendments/revisions to any study-related document or patient-safety related information, without prior approval of the EC
- ❖ To keep the EC informed of the study completion or discontinuation, with reasons
- ❖ To submit justification for approval to restart studies discontinued earlier by the EC

Yours sincerely,


Dr. Farha Rizwan
SECRETARY
Ethical Committee
M. C. E. Society
Azam Campus, Pune-1




Dr. P. M. Bulakh
CHAIRMAN
Ethical Committee
M. C. E. Society
Azam Campus, Pune-1.