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PARENT INFORMATION SHEET

Title of the study: Optimal vitamin D supplementation strategies for vitamin D deficient school children from North India.

Your child is being invited to take part in a research study. Before you and your family allow your child to participate in the study, it is essential to understand why this research is being done and what it will involve. Please take some time to read and understand the following information about the research. Please do not hesitate to ask us or discuss with us if anything is not clear. Thank you for reading this.

Vitamin D is an important hormone that is vital for optimal bone health. It is primarily obtained via sun exposure. The evidence regarding its beneficial role in extra-skeletal systems, such as prevention of Diabetes, metabolic syndrome, common cancers such as breast, colon and prostate etc, depression and autoimmune disorders, is fast accumulating from different parts of the world. Despite India being a tropical country, vitamin D deficiency is widely prevalent in Delhi school children. The primary reasons being, lack of adequate sun exposure, dark skin complexion, vegetarian food habits, sedentary life styles, atmospheric pollution, and lack of vitamin D supplementation & food fortification program. Our studies have shown a very high prevalence of vitamin D deficiency, ranging from 70-90% in healthy school going children with ten % of them having either bow legs or knock knee. There is, therefore, urgent need to address this problem of vitamin D deficiency not only in children but also in adults and elderly. In view of the above, International Life Sciences Institute, ILSI (India) and AIIMS have undertaken this project to evaluate the prevalence of vitamin D deficiency, and optimal vitamin D supplementation strategies to deal with vitamin D deficient Indian school children.

1. The aims of the present research study is to find out **a) the Daily Dietary Adequate Intake** of vitamin D in children of different age groups and gender **b) Evaluate the impact of supplementing vitamin D daily for six months in children who are deficient with regard to bone health and growth through clinical examination and estimation of vitamin D, PTH, Bone markers and growth factors in the blood pre and post supplementation.**
2. Participation is entirely voluntary. If you are willing to take part, you will be given this information sheet and asked to sign a consent form. Your child may also be asked to sign the consent form (if the child wishes to sign).
3. Only those children, whose parents give consent, will be recruited for participation in the study. They will undergo detailed anthropometric and clinical examination by super-

specialists (Endocrinologists) and five (5) ml (one teaspoon full) of blood will be collected at the beginning of the study. Those found to be vitamin D deficient, will be randomized and supplemented with different daily doses of vitamin D for a period of six months. Repeat blood samples will be collected post-supplementation, to evaluate the impact on bone health and growth. There is no risk involved in taking part in this study. There may be slight oozing of blood after sampling which can be controlled with firm pressure.

4. The ethical clearance for the study has been given by the Ethics Committee of AIIMS
5. When the research is completed, information resulting from the study will be given to you. All the information about your child during the course of the research will be kept strictly confidential.
6. The results of the study will be published in a scientific medical Journal as well as being presented at National and International meetings. However, any written or photographic material will not identify your child.
7. Children with any systemic disease or consuming calcium/vitamin D or any other drugs that affect bone health parameters, will be excluded from the study
8. All expenses incurred during the study will be met from the project funds. No child will have to pay for blood tests or vitamin D supplements.

Thank you for taking part in this study.

Contact for further information

Maj Gen (Dr) R K Marwaha
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Former Additional Director & Head, Department of Endocrinology
and Thyroid Research Centre INMAS, DRDO
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PRINCIPAL

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Consent Form

I have carefully read the details provided in the Parent Information Sheet regarding the objectives, methodology and benefits of the study being undertaken at A.G. DAV Centenary Public School, New Delhi. I hereby give my consent for my child to participate in the study.

Name of the child

Parent/Guardian Signature

Class & Section

School Registration No