Vitamin K status in Children with Osteogenesis Imperfecta

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We want to investigate whether blood levels of vitamin K are lower in children with O.I. compared to children without O.I.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON48934

Source
ToetsingOnline

Brief title
KinOI

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
Brittle bone disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Innovatiefonds zorgverzekeraars;stichting care for brittle bones en UMCU divisie kinderen cluster algemeen pediatrie

Intervention

Keyword: Bone, Children, Osteogenesis Imperfecta, Vitamin K

Outcome measures

Primary outcome

- vitamin K levels in blood

- osteocalcin levels in blood

- bone turnover markers in blood (i.e. Ntx (N-terminal telopeptide) & BAP

(Bone Alkaline Phosphatase))

Secondary outcome

N/A

Study description

Background summary

Children with the rare genetic disease Osteogenesis Imperfecta (O.I.) are prone to fracture bones. This latter is caused by a defect or decreased production of the protein in the bone that accounts for their strength, collagen-1. Because of this defective collagen, bones are degraded and build again faster compared to children without O.I. Optimal vitamin K levels are vital for bone quality and growth, however, the vitamin K status in children with O.I. it is currently unknown. Therefore, to investigate whether blood levels of vitamin K are lower in children with O.I. compared to children without O.I can provide new insights of bone quality and growth in this population. If levels are indeed lower compared to children with O.I. this could provide a relative simple window of opportunity to improve quality and growth of bone in these children as well as lowering the amount of fractures. Vitamin K can easily and safely be suppleted, but however has never been investigated in children with O.I. Therefore, the primary aim of the current study is to determine the vitamin K levels in children with O.I. and compare these compared to children without O.I.. If the vitamin K levels are decreased, we have sound scientific grounds to start a new study on the effects of vitamin K suppletion on bone strength and growth in children with O.I., which might result in fewer bone fractures, better growth, and quality of life.

Study objective

We want to investigate whether blood levels of vitamin K are lower in children with O.I. compared to children without O.I.

Study design

During 1 year children (0-18 y) with O.I. who regularly get bisphosphonate infusions at UMCU will be included in our study. We will use informed consent to ask for permission to take 1x a blood sample via the intravenous line. Parallel children who need to undergo surgery within the UMC Utrecht will be included in our study. The blood samples will be analyzed for Vitamin K and bone markers (by means of ELISA-like tests). Each blood sample that is collected, will be used to measure the named markers and results will be analyzed. At the end of project all data will be put together and a final analysis will be done Then, these results will be published in an international scientific journal and communicated to the OI patients via the patient support group (VOI)

Study burden and risks

We are interested in the vitamin K status of children with O.I., since they still grow and this is the period in life fractures are most common and the effect of possible vitamin K suppletion will be highest, when we find a vitamin K deficiency.
Blood (9 ml) is drawn once from the infuse line that is necessary for planned treatment during a regular visit to the center. This will therefore not induce extra pain or stress to the child. We expect that possible negative effects of blood withdrawal will be negligible: the child in every case will be lying down for some time after withdrawal because of the regular treatment that is started after our sampling.
The results will give direct indications about the possible deficiency of vitamin K in participating children. When a vitamin K deficiency is found in children with O.I., we will be able to start an intervention study with vitamin K shortly, since this supplement has been found already to be safe in adults as well as in children. When eventually would be proven that vitamin K has a positive effect on growth and amount of fractures in O.I., it will improve quality of life of children with O.I., possibly already the children that take part in our study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patients:
- Genetically confirmed Osteogensis Imperfecta (O.I.) type I-IV
- age 0-18 years
- at least once a year bisphosphonate infusions as part of regular care,
Controls:
- no O.I.
- age 0-18 years
- needing orthopaedic or ear, nose, throat surgery so that they will already get an infusion line.

Exclusion criteria

Patients:
- Not genetically confirmed O.I. type I-IV
- using vitamin K supplementation, Controls:
- known disease affecting vitamin K or bone turnover

- using vitamin K supplementation

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2018
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	21-03-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-09-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-11-2019
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL62582.041.17