

The effect of free vitamin D-drops and tailor-made information on serum 25-hydroxyvitamin D among infants of immigrant origin in Oslo, Norway: a randomised controlled trial

Submission date 08/11/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/12/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/03/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

Vitamin D-drops to infants with immigrant background

Study objectives

The main objective of the trial is to study whether free supply of vitamin D drops to six weeks old infants of immigrants from Pakistan, Turkey and Somalia together with tailor-made information handouts improves vitamin D status at the age of three months in the intervention group compared to a control group.

In addition, to study whether the information given also improves vitamin D status in the mothers in the intervention group compared to the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the ombudsman for privacy in research (ref: 200301024) on the 5th November 2003 and the Regional Committee for Medical Research Ethics (REK Sør) (ref: S-03196) on the 6th November 2003.

Study design

Open randomised controlled trial. Carried out at the Health Centre level. Health Centres were paired based on size. Randomisation was then carried out within each pair.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Vitamin D-deficiency

Interventions

Intervention group:

Provision of free vitamin D drops and instruction on how to administer it to their infants, including a tailored-made information brochure about vitamin D and its sources which have been translated to Urdu, Turkish and Somali.

Control group:

Usual care consisting of routine information about vitamin D and recommendation of use of vitamin D supplements, preferably cod liver oil.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Vitamin D supplementation

Primary outcome measure

1. Change in 25-hydroxyvitamin D from baseline (six week of age) to follow-up (three months of age) in the intervention group compared to the control group, adjusted for baseline level of 25-hydroxyvitamin D
2. Change in 25-hydroxyvitamin D from baseline to follow-up in the mothers in the intervention group compared to the mothers in the control group, adjusted for baseline level of 25-hydroxyvitamin D

Secondary outcome measures

Is there any difference between the groups at a second follow-up at eight months of age

Overall study start date

29/03/2004

Completion date

13/02/2006

Eligibility

Key inclusion criteria

1. Infants with Pakistani, Turkish or Somali background
2. Coming to routine consultation six weeks after birth in eight Health Centers in Oslo

Participant type(s)

Patient

Age group

Child

Sex

Not Specified

Target number of participants

48 participants (given randomization at the Health Center level)

Key exclusion criteria

Not applicable

Date of first enrolment

29/03/2004

Date of final enrolment

13/02/2006

Locations**Countries of recruitment**

Norway

Study participating centre

Institute of General Practice and Community Medicine

Oslo

Norway

0318

Sponsor information**Organisation**

The Directorate for Health and Social Affairs (Norway)

Sponsor details

Department of Nutrition

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Sponsor type

Government

ROR

<https://ror.org/01d2cn965>

Funder(s)

Funder type

Government

Funder Name

The Directorate for Health and Social Affairs, Oslo (Norway)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2011		Yes	No