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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
08/11/2006	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
14/12/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
31/03/2011	Nutritional, Metabolic, Endocrine			

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Prof Haakon E. Meyer

#### Contact details

Institute of General Practice and Community Medicine University of Oslo
P.O. Box 1130
Blindern
Oslo
Norway
0318
+47 480 82 702
h.e.meyer@medisin.uio.no

## Additional identifiers

#### Protocol serial number

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

### Study type(s)

Treatment

### 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(s)

- 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

#### Key secondary outcome(s))

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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Child

#### Sex

**Not Specified** 

#### 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)

#### **ROR**

https://ror.org/01d2cn965

## Funder(s)

### Funder type

Government

#### **Funder Name**

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

## **Results and Publications**

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