

The effect of vitamin D supplementation at diagnosis of pneumonia upon response to treatment

Submission date 27/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/03/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/10/2008	Condition category Respiratory	<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

Study objectives

There is no difference in the incidence of pneumonias or their severity for children diagnosed with pneumonia supplemented with 100,000 IU vitamin D at the start of the cold season and 3 months later compared to placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of the Ministry of Public Health of Afghanistan. Approved on 19 November 2006. Ref: 237783

Study design

Double blind randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Pneumonia

Interventions

Vitamin D3 100,000 IU supplementation vs placebo

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

vitamin D

Primary outcome measure

Duration of pneumonia as measured from the date of clinical diagnosis and treatment onset to the last date of illness with any of the following criteria:

1. Respiratory rate according to age and IMCI criteria
2. No danger signs or subcostal recession
3. No fever (temperature < 38.0 °C or < 37.50 °C if < 2 month old)

Secondary outcome measures

1. Incidence of further episodes within 3 months or relapse of pneumonia (The Integrated Management of Childhood Illness [IMCI] defined rapid breathing and cough)
2. Rate of failure to respond to treatment or worsening condition rate (as defined by protocol)

Overall study start date

09/12/2006

Completion date

30/05/2007

Eligibility

Key inclusion criteria

Any child, living in the defined areas of Kabul (within the catchment area of the Maywand Teaching Hospital), between 1 week and 18 complete months of age.

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Weeks

Upper age limit

18 Months

Sex

Not Specified

Target number of participants

450

Key exclusion criteria

1. >8 hours after the start of hospital antibiotics treatment
2. Living outside of the study areas of Kabul and child's families expect to move away within the next 3 months
3. If the child has been diagnosed with clinical rickets or known to have received a course of high dose vitamin D treatment in the past 3 months (doses as high as 300,000 IU are used routinely in

India and Pakistan, and thus rarely, some recently returned returnee children may have recently received such doses)

4. If have symptoms of very severe pneumonia (according to IMCI definitions of very severe pneumonia) or other illnesses as the major diagnosis occurring at the same time as pneumonia, such as meningitis, major heart or renal defect, active measles, severe malnutrition requiring separate medical treatment, and suspected tuberculosis

5. Child with severe diarrhoea or vomiting

6. Wheeze at the time of diagnosis (if wheeze develops later the child continues to be in the study)

7. Caretakers do not give consent

Date of first enrolment

09/12/2006

Date of final enrolment

30/05/2007

Locations

Countries of recruitment

Afghanistan

Study participating centre

Aga Khan Health Services Afghanistan

Kabul

Afghanistan

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Sponsor information

Organisation

Aga Khan Health Services Afghanistan (Afghanistan)

Sponsor details

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Sponsor type

Other

Funder(s)

Funder type

Government

Funder Name

New Zealand Aid and International Development Agency (New Zealand)

Funder Name

In kind donations from Aga Khan Development Network and Maywand Teaching Hospital (funded by the Government of Afghanistan) (Afghanistan)

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	01/01/2008		Yes	No