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The effect of vitamin A and zinc supplementation on the bacteriological response of persons with pulmonary tuberculosis in the Western Cape

Submission date 27/04/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/08/2007	**Overall study status** Completed	
Last Edited 01/09/2015	**Condition category** Infections and Infestations	

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
The effect of vitamin A and zinc supplementation on the bacteriological response of persons with pulmonary tuberculosis in the Western Cape

Study objectives
To investigate the efficacy of vitamin A and zinc supplementation for 2 months, in conjunction with standard anti-tuberculous therapy, on the bacteriological response of adults with newly diagnosed smear-positive pulmonary tuberculosis.

In South-Africa tuberculosis accounts for more than 80% of all communicable diseases and is regarded as one of the most serious health problems affecting the country. There are an estimated 556 cases per population of 100,000 each year, with the highest incidence in the Western Cape. HIV infection is the greatest individual risk factor for tuberculosis and more than half of smear-positive patients are HIV-infected in South Africa. A recent Indonesian study investigated the combined effect of vitamin A and zinc supplementation to adults with pulmonary tuberculosis. Conversion of positive sputum smears was significantly faster in the micronutrient group than in the placebo group after 2 months of anti-tuberculosis treatment. Earlier sputum conversion is critical in terms of tuberculosis control in South Africa. Our study will therefore aim to determine the efficacy of a low cost micronutrient intervention on short-term outcomes such as bacteriological and immunological responses as well as clinical and nutritional parameters in smear positive adult pulmonary TB patients within the context of co-infection with HIV.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research and Ethics Committee at the University of Cape Town, 08/03/2005, ref: REC 137/2003

Study design
Randomized double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pulmonary tuberculosis

Interventions
Patients will be randomly assigned to the following two groups:

Intervention group: A single dose of 200 000 IU vitamin A (capsule, orally) at study entry plus daily supplementation of 15 mg zinc (tablet, orally) for 2 months
Control group: Placebo capsules (orally) at study entry plus daily placebo tablets (orally) for 2 months.

Both groups will receive standard anti-tuberculosis treatment in addition to the supplement or placebo.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
vitamin A and zinc

Primary outcome measure
Sputum smear and culture conversion rates, measured every week up to 8 weeks.

Secondary outcome measures
The following will be assessed at baseline, 2 and 8 weeks:
1. Radiologic resolution
2. Anthropometrical status (body mass index, arm muscle circumference, percentage body fat)
3. Serum micronutrient levels (retinol, zinc, iron and copper)
4. Performance status (Karnofsky scale)
5. Immunological parameters (Interferon-gamma)

Overall study start date
01/04/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Patients with newly diagnosed smear-positive pulmonary tuberculosis attending community health care centres in Delft, Cape Town.

Participant type(s)
Patient

Age group
Not Specified

Sex

Not Specified

Target number of participants
182

Key exclusion criteria
1. Re-treatment patients
2. Patients with extra-pulmonary tuberculosis
3. Patients with Multi-Drug Resistance (MDR) at baseline or during follow-up
4. Patients with elevated alanine transaminase levels (>5 fold increase)
5. Women who are pregnant or wish to become pregnant
6. Women who have given birth within 6 months of study entry
7. Patients with clinical signs of liver disease, renal failure, congestive heart failure or neoplasm
8. Use of corticosteroids
9. Use of supplements containing vitamin A, zinc or iron during the previous month prior to treatment
10. No consent given for a voluntary HIV-test at baseline

Date of first enrolment
01/04/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
South Africa

Study participating centre
PO Box 6614
Cape Town
South Africa
7538

Sponsor information

Organisation
University of the Western Cape, School of Public Health, Division of Dietetics (South Africa)

Sponsor details
Division of Dietetics
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Sponsor type
University/education

ROR
https://ror.org/00h2vm590

Funder(s)

Funder type
Not defined

Funder Name
National Research Foundation, South Africa Institutional Research Development (grant number: 2067444)

Funder Name
The Norwegian Programme for Development, Research and Higher Education Network (grant number: NUFUPRO-2007/10183)

Funder Name
South African Sugar Association Nutrition Research (grant number: 200)

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
Results article	results	01/01/2015		Yes	No