

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	<input type="checkbox"/> Prospectively registered
Registration date 13/08/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/09/2015	Condition category Infections and Infestations	<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

Contact name

Mrs Marianne Emilie Visser

Contact details

PO Box 6614
Welgemoed
Cape Town
South Africa
7538

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

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