

Antifungal medication improves treatment of sarcoidosis

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Registration date 29/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/05/2013	Condition category Haematological Disorders	<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
Dr Marjeta Tercelj

Contact details
University Medical Center
Zaloska 7
Ljubljana
Slovenia
1000
+386 (0)1 5222342
marjeta.tercelj@kclj.si

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Antifungal medication improves treatment of sarcoidosis: A three arm, randomised controlled trial

Acronym

AFS

Study objectives

Treatment with antifungal agents would be more efficient than treatment with corticosteroids only

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the ethical committee at the University Medical Centre, Ljubljana, Slovenia (ref: 85 /05/04)

Study design

Single centre 3 arm randomised active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pulmonary sarcoidosis

Interventions

1. Corticosteroid (12 - 16 mg methylprednisolone every second day)
2. Itraconazol (200 mg daily)
3. Corticosteroid and Itraconazol in combination

Patients were controlled at 2-3 months. The total duration of treatment was 6 months and the effect of the treatment was evaluated at the end of this time.

Results:

The X-ray score decreased significantly more among subject who received antifungal medication, with or without corticosteroids. The results thus suggest that the antifungal treatment is efficient against the causative agent in sarcoidosis.

Intervention Type

Other

Phase

Phase IV

Primary outcome(s)

1. X-ray was taken before and after treatment. A grading scheme for the presence of granulomas was used as described previously. The x-rays were read by two experienced radiologists, unaware of the status of the patient, grading granulomas according to a numerical score (0-4), judging size and extension of the infiltrates (0 = normal, 1= ca 25% of lung field involved, 2 = up to 50%, 3 = up to 75%, and 4 = virtually the whole lung field involved). Repeat evaluations on two successive occasions showed only minor deviations in the classification.

2. Diffusing Capacity of the Lung for Carbon Monoxide (DLCO) was measured using standard techniques
3. Inflammatory indicators of sarcoidosis were determined
 - 3.1. The soluble IL-2 receptor (sIL-2R) in serum was quantified using an ELISA commercial kit (Milenia Biotech, Badnaheim, Gemany) and expressed as U/mL
 - 3.2. Angiotensin converting enzyme in serum (sACE) was determined using a colorimetric method and expressed as iKat/L
 - 3.3. Chitotriosidase (CTO) activity in serum was determined

Key secondary outcome(s)

None

Completion date

31/07/2010

Eligibility

Key inclusion criteria

1. Subjects with sarcoidosis diagnosed using established criteria at the Department of Pulmonary and Allergic diseases at the Medical Center, University hospital of Ljubljana, Slovenia.
2. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Severe sarcoidosis requiring immediate treatment

Date of first enrolment

15/08/2003

Date of final enrolment

31/07/2010

Locations

Countries of recruitment

Slovenia

Study participating centre
University Medical Center
Ljubljana
Slovenia
1000

Sponsor information

Organisation
University Hospital, Ljubljana (Slovenia)

ROR
<https://ror.org/01nr6fy72>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ljubljana Medical Centre (Slovenia) - Clinic of Respiratory Disease and Allergy

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	01/06/2011		Yes	No