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Antifungal medication improves treatment of sarcoidosis

Submission date	Recruitment status	[_] Prospectively registered
08/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/05/2013	Haematological Disorders	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patients received oral advice, therefore patient information sheet is not available. Contact [envhealth@biofact.se] for further information.

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 measure
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, Badnauheim, Gemany) and expressed as U/mL
3.2. Angiotensin converting enzyme in serum (sACE) was determined using a colorimetric method and expressed as ìKat/L
3.3. Chitotriosidase (CTO) activity in serum was determined

Secondary outcome measures
None

Overall study start date
15/08/2003

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

Age group
Adult

Sex
Both

Target number of participants
20

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
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Sponsor information

Organisation
University Hospital, Ljubljana (Slovenia)

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Sponsor type
Hospital/treatment centre

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

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	01/06/2011		Yes	No