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Rituximab In Psoriatic Arthritis: a multi-centre randomised placebo-controlled double blind pilot-study of rituximab in patients with active psoriatic arthritis

Submission date	Recruitment status	[ ] Prospectively registered
01/09/2006	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
21/12/2006	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
21/12/2006	Musculoskeletal Diseases	[ ] Record updated in last year

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
1.1

Study information

Scientific Title

Acronym
RIPA

Study objectives
To investigate the efficacy and safety of treatment with rituximab in patients with active Psoriatic Arthritis (PsA) who showed at last one Disease Modifying Anti-Rheumatic Drug (DMARD) failure (phase IIb, efficacy and dose finding).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee and internal review board of the Medical University of Vienna (reference number 049/2006), date of approval: 14/03/2006.

Study design
A multi-centre placebo-controlled, double blind randomized study of Rituximab (MabThera®) in patients with active Psoriatic Arthritis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Psoriatic Arthritis (PsA)

Interventions
Infusion with Rituximab (MabThera®)

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Rituximab (MabThera®), methotrexate (MTX)

Primary outcome measure
Primary endpoint is the Psoriatic Arthritis Response Criteria (PsARC): improvement of 30% of tender and swollen joint count or if only one fulfilled, then plus 30% improvement of Visual Analogue Scale (VAS) patient global or physican global.

Secondary outcome measures
1. Psoriasis Area and Severity Index
2. Disease Activity Score based on 28 joints (DAS28)
3. Simplified Disease Activity Index (SDAI)
4. Clinical Disease Activity Index (CDAI)
5. Disease Activity index for the assessment of Reactive Arthritis (DAREA)
6. Health Assessment Questionnaire (HAQ)
7. Short Form health survey (SF-36)

Overall study start date
01/09/2006

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. Patients diagnosed with PsA according to the following criteria: psoriasis or family history of psoriasis plus any one of the following criteria:
a. clinical inflammatory enthesitis
b. radiographic enthesitis
c. distal interphalangeal joint disease
d. sacroiliitis or spinal inflammation
e. dactylitis
f. monoarthritis
g. oligoarthritis (four or less swollen joints)
2. Aged 18 years or older
3. Negative rheumatoid factor
4. The disease should at least have been diagnosed six months prior to screening
5. Active disease at the time of screening as defined by:
a. two out of the following three criteria:
i. more than or equal to four swollen on a 66/68 joint count
ii. more than or equal to six tender joints on a 66/68 joint count
iii. presence of dactylitis
b. and one out of the following two categories:
i. Erythrocyte Sedimentation Rate (ESR) more than or equal to 28 mm/h
ii. C-Reactive Protein (CRP) more than or equal to 1.0 mg/dl
6. Insufficient response to MTX in maximum tolerated dose

7. All patients use MTX and must be on a stable dose prior to screening
8. Patients must be receiving concurrent therapeutic folic acid
9. Patients using oral corticosteroids must have been on a stable dose of less than or equal to 10 mg/day for two weeks prior to screening. If using Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), patients must be on a stable dose for two weeks prior to screening
10. Women of childbearing potential or men capable of fathering children must be using adequate birth control measures (e.g., abstinence, oral contraceptives, intrauterine device, barrier method with spermicide, surgical sterilisation) during the study and for six months after receiving the last administration of study agent
11. Female subjects of childbearing potential must test negative for pregnancy. A pregnancy test will be performed at the beginning and at the end of the study
12. The screening laboratory test must meet the following criteria:
a. haemoglobin more than or equal to 8.5 g/dl providing the low haemoglobin level is not due to other diseases than anemia of chronic inflammation
b. White Blood Cells (WBC) more than or equal to 3500/µl
c. neutrophils more than or equal to 1500/µl
d. platelets more than or equal to 100,000/µl
e. serum transaminase less than or equal to two times the Upper Limit of Normal
f. serum creatinine less than or equal to 1.7 mg/dl
13. The patient must be able to adhere the study visit schedule and other protocol requirements and must have given informed consent prior to any screening procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Patients are excluded if they meet one of the following criteria:
1. Pregnant women, nursing mothers or a planned pregnancy within six months after last scheduled treatment
2. Patients with other inflammatory diseases that might interfere with the evaluation of the psoriatic arthritis
3. Patients with fibromyalgia syndrome
4. Use of Rituximab prior to screening
5. Treatment with Tumor Necrosis Factor (TNF)-Blockers prior to screening
6. Use of IntraMuscular (IM), IntraVenous (IV), Intra-Arterial (IA) corticosteroids within four weeks prior to screening
7. Treatment with any investigational drug within three months prior to screening
8. Use of cyclosporine or tacrolimus within four weeks prior to screening
9. A history of known allergy to murine proteins, e.g. allergy to Infliximab

10. History of infected joint prosthesis within the previous five years
11. Chronic infections
12. History of active TuBerculosis (TB) requiring treatment within the previous three years, or history of opportunistic infections within two months, uncontrolled active infection or documented Human Immunodeficiency Virus (HIV) infection. Also excluded are patients with evidence of latent TB and patients with old TB without documented adequate therapy if they will not be treated according to the local TB guidelines
13. Current signs or symptoms of other severe uncontrolled disease which in the investigators opinion would put the patient at an unacceptable risk
14. History of lymphoproliferative disease, any current malignancies or history of malignancy within five years other than successfully treated basal cell carcinoma or squamous cell carcinoma of the skin
15. History of drug abuse

Date of first enrolment
01/09/2006

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
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Sponsor information

Organisation
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Sponsor type

University/education

Website
http://www.meduniwien.ac.at/

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Other

Funder Name
The trial is an investigator driven study without any grant support, Roche provides the medication.

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