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BIOmarker-driven DEcision Study with Adalimumab (BIODESA)

Submission date	Recruitment status	[X] Prospectively registered
29/07/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/09/2008	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
N/A

Study information

Scientific Title
Individualised therapy of rheumatoid arthritis with anti-tumour necrosis factor (TNF) antibodies (adalimuab) based on neuroendocrine biomarkers, a prospective clinical study

Acronym
BIODESA

Study objectives
Patients with a biomarker value (cortisol/adrenocorticotropic hormone [ACTH]) below 196,000 are responders to adalimumab treatment as demonstrated by a significantly better outcome (Disease Activity Score using 28 joints [DAS28]). The ratio of serum cortisol/serum ACTH can be used as a biomarker.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application was submitted to the Ethics Committee of the University of Regensburg on 20/07 /2008. Approval expected to be granted in October 2008.

Study design
Phase III, non-randomised, double-blind (participants and physicians), two-arm, controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
The participants will be allocated to two groups according to a biomarker; the biomarker is the ratio of serum levels (in mol/l) of cortisol divided by ACTH (cortisol/ACTH). Both groups are treated with the already approved anti-TNF antibody adalimumab 40 mg subcutaneously (s.c.) every other week for 24 weeks. The patients and the treating physicians do not know the group allocation.

We expect that patients with a cortisol/ACTH ratio above 196,000 do not profit much from the anti-TNF therapy, whereas those patients with a ratio below 196,000 will profit from

adalimumab therapy. According to good clinical care guidelines, we will have a rescue line at week 12. Those patients that do not profit from the therapy are switched to standard DMARD therapy with methotreaxte and prednisolone.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Adalimuab

Primary outcome measure
DAS28 at 12 weeks.

Secondary outcome measures
1. Response to hormonal challenge test (corticotropin releasing hormone [CRH], growth hormone releasing hormone [GHRH], thyrotropin releasing hormone [TRH], and luteinizing hormone releasing hormone [LHRH] before and after anti-TNF therapy)
2. Behaviour of circadian rhythm curves of cortisol, testosterone, and DHEA (before and after anti-TNF therapy)
3. Volume and morphology of the adrenal glands (magnetic resonance imaging [MRI] before and after anti-TNF therapy)
4. Volume of the anterior cingulate cortex (MRI before and after anti-TNF therapy)
5. Expression of 11-betahydroxysteroid-dehydrogenase type 2 as investigated in miniarthroscopically removed synovial tissue (before and after anti-TNF therapy)

Overall study start date
01/01/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Rheumatoid arthritis (RA) is diagnosed according to the American College of Rheumatology criteria
2. Both males and females, age must be 18 years or older
3. Patients must have given written informed consent
4. The disease duration should be less than 24 months
5. The DAS28 score must be above 5.0
6. The number of swollen joints must be >=8
7. The number of tender joints must be >=10
8. The erythrocyte sedimentation rate must be >=28 mm/hour

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Other inflammatory arthropathies such as psoriasis arthritis and similar conditions
2. Treatment with disease modifying anti-rheumatic drugs (DMARDs), glucocorticoids, or biologics
3. Severe or uncontrolled comorbidities (e.g. infectious, metabolic, hepatic, cardiac, malignant, psychiatric comorbidities)
4. A positive screening test result for tuberculosis (purified protein of tuberculin 5 [PPD5] test, chest radiography). Patients at high risk for tuberculosis are excluded or are treated with isoniazid up to 300 mg/day concomitantly.
5. Patients of child-bearing potential without adequate contraceptive protection
6. Patients with contraindications for trial drugs

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Germany

Study participating centre
Franz-Josef-Strauss-Allee 11
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Sponsor information

Organisation
University Hospital Regensburg (Universitätsklinikum Regensburg) (Germany)

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Sponsor type
Hospital/treatment centre

Website
http://www.uniklinikum-regensburg.de

ROR
https://ror.org/01226dv09

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Regensburg (Universitätsklinikum Regensburg) (Germany)

Funder Name
German Research Foundation (Deutsche Forschungsgemeinschaft) (Germany) - Decision pending

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