

BIOmarker-driven DEcision Study with Adalimumab (BIODESA)

Submission date 29/07/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/09/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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/adrenocorticotrophic 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

Intentional

Study type(s)

Treatment

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 methotrexate and prednisolone.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Adalimumab

Primary outcome(s)

DAS28 at 12 weeks.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Regensburg

Germany

93042

Sponsor information

Organisation

University Hospital Regensburg (Universitätsklinikum Regensburg) (Germany)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration