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# Comparative analysis of adult-onset Still's disease (AOSD) treatments

**Submission date**
12/12/2023

**Recruitment status**
No longer recruiting

**Registration date**
14/12/2023

**Overall study status**
Completed

**Last Edited**
14/12/2023

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Adult-onset Still’s disease (AOSD) is a rare autoinflammatory disorder with increased mortality. Complications such as macrophage activation syndrome in continuously active disease carry a high mortality risk. Glucocorticoids (GC) and conventional disease-modifying antirheumatic drugs (DMARDs) are commonly used as first-line therapeutic options as opposed to recently licensed interleukin-1 (IL1)-receptor antagonist anakinra (ANA), neutralizing IL1b-antibody canakinumab (CAN), or non-licensed use of IL-6 receptor antibody tocilizumab (TCZ). However, DMARDs have a considerably slower onset, and GC may result in substantial side-effects such as diabetes mellitus or osteonecrosis of the hips. Our study evaluates potential benefits of biologicals (ANA, CAN, TCZ) as first-line therapeutic options in AOSD.

Who can participate?
Data from AOSD-patients (disease onset) fulfilling the Yamaguchi classification criteria, over 18 years, female/male or divers of the last 15 years of participating centers are included in the study.

What does the study involve?
We plan to retrospectively analyze data from German rheumatology centers (last 15 years), examining both the effectiveness of therapy (percentage of patients in remission) and side effects of different therapies.

What are the possible benefits and risks of participating?
Participating in this study offers the benefit of contributing valuable data to guide treatment decisions for AOSD patients, including insights into treatment responses and potential complications under various treatment options.

Where is the study run from?

When is the study starting and how long is it expected to run for?
January 2023 to January 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr. A. Kernder, anna_kernder@t-online.de

# Contact information

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Comparison of different treatments in adult-onset Still's disease (AOSD): biologics, glucocorticoids, and conventional disease-modifying antirheumatic drugs (DMARDs)

### Acronym
TAST

### Study objectives
Complication free remission rates are lower in patients initially treated with biological therapy as opposed to DMARD therapy

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 13/09/2023, Ethics Committee of the medical faculty of the University of Duesseldorf (Moorenstr. 5, Düsseldorf, 40225, Germany; +49 211 81-19591; ethikkommission@med.uni-duesseldorf.de), ref: 2023-2423

### Study design
Retrospective chart review of AOSD patients from multiple German centers

### Primary study design
Observational

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Treatments of Adult-onset Still's Disease (AOSD, rheumatic disease)

### Interventions
Retrospective Observational study

Data collected:
- Epidemiological data (age at onset, sex, height, weight, comorbidities)
- Disease activity data (items of the Pouchot Score, CRP, Ferritin, Leukocyte count, alternatively the EULAR-DAVID score if available in the meantime)
- Physician subjective evaluation of “remission” based on chart review
- fever yes/no
- arthritis yes/no
- ASOD-associated rash yes/no
- Treatment
- Complication of GC use:
Diabetes necessitating insulin therapy Gain in body weight (≥ 10%) Osteonecrosis of any joint

Psychosis or other psychiatric disease requiring psychopharmacological intervention
Hypertension
Dyslipidemia requiring therapy with e.g. statins
Worsening of bone density > 0,5 SD (T1-4, neck or total hip)
Clinical diagnosis of steroid myopathy Skin disease attributed to GC
Eye disease attributable to
- Serious infection necessitating intravenous antibiotic use
- Death
- Macrophage activation syndrome
- AOSD-associated pneumonitis
- ASOD-associated perimyocarditis
- Ongoing disease activity requiring switch from DMARD-based to biological therapy

## Intervention Type
Other

## Primary outcome(s)
Sustained remission (definition see below) at week 12 and complication free until week 72 (definition see below).

For remission, all of the below must be fulfilled:
1. Physician subjective evaluation of “remission” based on chart review
2. CRP below 10 mg/l
3. No fever during last week
4. No arthritis during last week
5. No ASOD-associated rash during last week

For Complication-free (none of the following should have been appeared):
1. Complications of GC use
2. Diabetes necessitating insulin therapy
3. Gain in body weight (≥ 10%)
4. Osteonecrosis of any joint
5. Psychosis or other psychiatric disease requiring psychopharmacological intervention
6. Hypertension > 180 mmHg systolic pressure resulting in change of antihypertensive medication
7. Dyslipidemia requiring therapy with e.g. statins
8. Worsening of bone density > 0,5 SD (T1-4, neck or total hip), preexisting osteoporosis or osteoporosis diagnosed within 2 months of disease onset is not considered to be a GC-related event
9. Clinical diagnosis of steroid myopathy
10. Skin disease attributed to GC, e.g. striae, cutaneous necrosis, relevant subcutaneous bleeding or ulcerations
11. Eye disease attributable to GC (esp. cataract, glaucoma)
12. Serious infection necessitating intravenous antibiotic use
13. Death
14. Development of macrophage activation syndrome, AOSD-associated pneumonitis, ASOD-associated peri myocarditis
15. Ongoing disease activity requiring switch from DMARD-based to biological therapy

## Key secondary outcome(s))

1. Flare-free survival in patients under remission
2. Rate of remission (definition see below) by week 12 and complication free by week 72
3. Retrospective analysis of differences in the glucocorticoid toxicity index (GTI)
4. GC dose reduction (at week 12 and week 72)
5. GC dose reduction by at least 75% compared to disease onset
6. Time to remission
7. Time to complication (definition see above)
8. Complications (definition see above)

### Completion date
31/01/2024

## Eligibility

### Key inclusion criteria
1. Yamaguchi classification criteria are met
2. Documented clinical visits at onset/flare, by week 12 and week 72

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
Not matching the inclusion criteria

### Date of first enrolment
15/09/2008

### Date of final enrolment
31/01/2024

## Locations

### Countries of recruitment
Germany

**Study participating centre**
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# Sponsor information

**Organisation**
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# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**
The raw data supporting the conclusions will be made available by the authors on reasonable request.
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**IPD sharing plan summary**
Available on request