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

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
12/12/2023		☐ Protocol	
Registration date 14/12/2023	Overall study status Completed  Condition category Musculoskeletal Diseases	Statistical analysis plan	
		Results	
Last Edited		Individual participant data	
14/12/2023		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

#### Type(s)

Principal investigator

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Public, Scientific

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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.uniduesseldorf.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

Rheinisches Rheuma-Zentrum St. Elisabeth-Hospital Meerbusch

Hauptstr. 74-76 Meerbusch-Lank Germany 40668

#### Study participating centre

Klinik für Rheumatologie und Hiller Forschungszentrum, Uniklinik Düsseldorf, Medizinische Fakultät, Heinrich-Heine Universität

Moorenstraße 5 Düssseldorf Germany 40225

#### Study participating centre

III Department of Medicine, University Medical Center Hamburg-Eppendorf

Martinistraße 52 Hamburg Germany 20251

#### Study participating centre

Rheumazentrum Sachsen-Anhalt, Kooperationspartner der Otto-von-Guericke Universität Magdeburg, Helios Fachklinik Vogelsang-Gommern

Sophie-von-Boetticher-Str. 1 Vogelsang-Gommern Germany 39245

## Study participating centre

Medizinische Klinik 3 - Rheumatologie und Immunologie, Universitätsklinikum Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU)

Ulmenweg 18 Erlangen Germany 91054

## Study participating centre

Medizinische Klinik 5, Sektion Rheumatologie, Universitätsklinikum Heidelberg

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### Study participating centre Medizinische Hochschule Hannover MHH

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#### Study participating centre

Abt. Rheumatologie, klin. Immunologie, Osteologie und Physikalische Medizin, Campus Kerckhoff der Justus-Liebig-Universität Gießen

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#### Study participating centre Universitätsklinikum Tübingen, Innere Medizin/Rheumatologie

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# Study participating centre Rheumazentrum Halle Universitätsmedizin Halle

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# Sponsor information

#### Organisation

St. Elisabeth-Hospital Meerbusch-Lank

# 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

#### **Study outputs**

Output type	Details	Date created	Date added Peer reviewe	ed? Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes