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Helping people with rheumatoid arthritis to stop smoking - a multicentre study

Submission date
29/08/2025

Recruitment status
No longer recruiting

Registration date
23/10/2025

Overall study status
Completed

Last Edited
23/10/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Rheumatoid arthritis (RA) is a chronic autoinflammatory disease that accompanies affected patients for many years. The exact causes of RA are not yet fully understood. However, it is known that certain factors influence the disease, such as smoking. We now aim to examine whether a specific counselling technique (quick verbal smoking intervention) can support smoking cessation and how this may affect disease control (disease activity, quality of life, antirheumatic medication).

Who can participate?
Outpatients and inpatients (age 18 years or above) with RA from St. Elisabeth-Hospital Meerbusch-Lank or from University Hospital Düsseldorf, who had smoked at least five conventional cigarettes per day during the week prior to participation.

What does the study involve?
The study will last about 48 weeks and include three clinic visits: at baseline, after 12 weeks, and after 48 weeks. These visits will take place during the patients' regular appointments, so no extra travel or cost is required. At each visit, patients will be asked to complete a questionnaire (about 15 minutes), and exhaled carbon monoxide will be measured with a short breath test that takes only a few seconds. At the baseline visit, a brief counselling session of up to five minutes will also be conducted after the physician's appointment.

What are the possible benefits and risks of participating?
If patients succeed in reducing or quitting cigarette consumption, positive effects on disease activity and a reduction in rheumatic symptoms can be expected. Participation in the study does not involve any additional costs or travel for patients, as both the counselling sessions and the completion of questionnaires will take place during their regular appointments. No known risks or burdens are expected.

Where is the study run from?
The study is run from St. Elisabeth-Hospital Meerbusch-Lank (Germany)

When is the study starting and how long is it expected to run for?
June 2024 to April 2026.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Dr med. Stefan Vordenbäumen, stefan.vordenbaeumen@rrz-meerbusch.de

Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
V02QuiSIRA062024

Study information

Scientific Title
A multicentre randomized controlled trial of a brief smoking cessation intervention in patients with rheumatoide arthritis compared to usual care: effects on smoking behaviour and disease activitiy (QuiSIRA - Quick Smoking Intervention in active smoking Rheumatoid Arthritis patients)

Acronym
QuiSIRA

Study objectives
It will be examined whether a quick verbal smoking intervention leads to higher smoking cessation rates among patients with rheumatoid arthritis and improves disease control (disease activity, quality of life, antirheumatic medication).

Working hypothesis: The quick verbal smoking intervention is superior to providing information alone about the relationship between smoking and rheumatoid arthritis with regard to smoking cessation rates.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/06/2024, Ethics Committee of the Medical Faculty, Heinrich Heine University Düsseldorf (Moorenstraße 5, Düsseldorf, 40225, Germany; +49 2118119591; Ethikkommission@med.uni-duesseldorf.de), ref: 2024-2806

Study design
Multicenter interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Rheumatoid arthritis and nicotine consumption

Interventions
To assess whether a quick smoking intervention can support smoking cessation in patients with rheumatoid arthritis, participants will be randomly assigned to one of two groups. In the intervention group, a quick smoking intervention using motivational interviewing will be applied in combination with information on the relationship between smoking and RA (usual care). In the control group, only usual care will be provided.

Each participant will be in the study for approximately one year.
- Baseline visit: participants complete a questionnaire (~15 minutes) and a short interview (~5-10 minutes).
- Follow-up visits at 12+- 6 weeks and 48 +-6 weeks: only the questionnaire is completed (each ~15 minutes).
- Follow-up visits are aligned with the patients' routine appointments at the rheumatology outpatient clinic.

Recruitment and randomisation:
Patients were approached during their outpatient clinic visits or during an inpatient stay and asked about their interest in the study. Randomisation was performed by assigning patients alternately to the study groups.

Intervention Type
Behavioural

Primary outcome(s)
Non-smoking rate at 12 (+/- 6) weeks (seven-day point prevalence abstinence) measured by questionnaires

Key secondary outcome(s))
1. Disease activity measured using DAS28 CRP at week 12 and week 48
2. Flare rate defined as increase or initiation of ≥ 5 mg daily prednisone or change of medication or new medication at week 12 and week 48
3. Health-related quality of life measured by VR 12-questionnaire at week 12 and week 48
4. Antirheumatic medication at week 12 and week 48 measured by questionnaires
5. Nicotine dependence measured by Fagerström-questionnaire at week 12 and week 48
6. Number of abstinence attempts measured by questionnaires at week 12 and week 48
7. Carbon monoxide measured by Micro+Tm Smokerlyzer at week 12 and week 48
8. Lifestyle information measured by MEDAS-questionnaire and physical activity assessment at week 12 and week 48
9. Number of cigarettes smoked per day at week 12 and week 48 measured by questionnaires
10. Seeking of additional support since week 0 (e.g. hypnosis, acupuncture, smoking cessation counselling) measured by questionnaires

Completion date
06/04/2026

Eligibility

Key inclusion criteria
1. Diagnosis of RA according to ACR/EULAR criteria, no overlap syndromes except for secondary Sjögren Syndrom allowed
2. Outpatients/ inpatients (age >18 years) from St. Elisabeth-Hospital Meerbusch-Lank and from

University Hospital Düsseldorf
3. Active cigarette smoking patients (at least five conventional cigarettes per day in the last week)
4. Sufficient proficiency in German language (at least C1) as judged by the intervenor

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Total final enrolment
124

Key exclusion criteria
1. Occasional smokers (less than five conventional cigarettes per day in the last week)
2. Use of vaporizers only
3. Use of tabacco heaters only
4. Prior structured smoking intervention:
5. Prior structured quick smoking intervention (to the best of the patient’s knowledge)
6. Prior alternative smoking intervention treatments such as hypnosis or acupuncture
7. Nicotine replacement therapy at the moment (nicotine-containing patches, chewing gum, lozenges, sprays, inhalers)
8. Medication for smoking cessation at the moment (Bupropion, Cytisin, Vareniclin)

Date of first enrolment
26/06/2024

Date of final enrolment
11/06/2025

Locations

Countries of recruitment
Germany

Study participating centre
St. Elisabeth-Hospital Meerbusch-Lank
Hauptstraße 74-76
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Study participating centre
Universitätsklinikum Düsseldorf
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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 datasets generated during and/ or analysed during the current study will be available upon request from (Prof. Dr. med. Stefan Vordenbäumen, stefan.vordenbaeumen@rrz-meerbusch.de)

IPD sharing plan summary
Available on request