Development and validation of an epigenetic biomarker that predicts treatment success and allows personalized management in rheumatoid arthritis and psoriasis

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Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON56905

Source
ToetsingOnline

Brief title
EPIPSORA

Condition

- Autoimmune disorders
- Synovial and bursal disorders
- Epidermal and dermal conditions

Synonym
psoriasis, rheumatoid arthritis (rheumatoid)

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: De Europese unie (Horizon Europe)

Intervention

Keyword: Biologicals, DNA methylation markers, Psoriasis, Rheumatoid arthritis

Outcome measures

Primary outcome

Clinical efficacy will be measured according to routine care. Percentage of patients meeting established and validated endpoints for good treatment response: clinical disease activity index (CDAI) <10.1 and *CDAI>=50% at Week 12 for RA and Absolute Psoriasis Area and Severity Index (PASI) score <=2 at Week 26 for PsO will be calculated. Epigenetic patterns of predictor CpGs associated with treatment response will be established.

Secondary outcome

Not applicable.

Study description

Background summary

Current biological treatment options for rheumatoid arthritis (RA) and psoriasis (PsO) only reaches remission in <50% of the patients. Currently, these patients are treated with a *trial and error* approach because no validated predictors are available for therapeutic success. This has a major impact on both patient morbidity as well as direct and indirect health care costs. Based upon success in Crohn*s disease and a discovery study in RA, we propose to perform an observational study for the development and validation of an epigenetic biomarker that can predict treatment success in RA and PsO.

Study objective

The main objective of the study is to establish epigenetic patterns of predictor 5*-C-phosphate-G-3* (CpGs) in peripheral blood that are associated with (non-)response to 3 commonly used biologics to treat RA and PsO. Methylation profiles will be compared between objective responders and non-responders.

Study design

This is a multi-centre, observational, prospective study (with the aim to identify methylation patterns that can predict treatment response to biologics). The medical treatments are available in all participating countries with comparable Summary of Product Characteristics (SPC) and will be used in the frame of their label and according to common clinical practice in regular routine care. Sites will ship 1 tube of whole blood of individual patients (collected at baseline) to the Amsterdam University Medical Centres, where DNA will be isolated and methylation patterns determined.

Study burden and risks

Participants will receive biological treatment as part of their routine care. The focus will lie on parameters that reflect response/non-response to treatment (CDAI for RA, PASI for PsO). These procedures belong to the standard of care and are not associated with additional burden for the patient. We ask additional blood collection for the determination of methylation patterns, drug concentrations and anti-drug antibodies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosis of rheumatoid arthritis or psoriasis
- Active symptomatic disease
- Indication for biologic treatment with adalimumab (both), tocilizumab (RA), abatacept (RA), ustekinumab (PsO) or secukinumab (PsO)

Exclusion criteria

- Any condition which, in the opinion of the investigator, may interfere with the patient's ability to comply with study procedures
- Received any investigational drug or another biologic in last month

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	31-07-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85133.018.23