Treatment of severe gout patients with rasburicase

Published: 22-03-2023
Last updated: 18-01-2025

The primary outcome parameter is the Gout Activity Score (GAS)after 6 months of rasburicase treatment. Secondary outcome parameters are the serum uric acid concentration, the clinical evaluation of tophus load, patient reported outcomes: MD-HAQ, GAQ...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON53559

Source
ToetsingOnline

Brief title
TRACE

Condition

- Joint disorders

Synonym
Gout, inflammatory joint disease

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Jan van Breemen Instituut,Reade foundation;Sanofi,Sanofi-aventis

Intervention

Keyword: Antibody, Gout, Rasburicase

Outcome measures

Primary outcome

The primary outcome is Gout Activity Score after 6 months of rasburicase treatment.

Secondary outcome

Secondary outcomes will consist of serum uric acid concentration, a clinical evaluation of tophus load, patient reported outcome measures; MD-HAQ, GAQ and safety measures (AE/SAEs), anti-drug antibody titers and to investigate B-cells response against rasbirucase.

Study description

Background summary

Gout is the most prevalent inflammatory rheumatic disease. Treatment of gout in primary care, as well as in a hospital setting is often suboptimal. Adherence to therapy is generally poor and treatment is often limited to acute attacks rather than adequately treating gout with urateFurthermore, even a substantial number of patients on urate lowering therapy cannot reach serum urate target due to intolerance, lack of effect, or co-morbidity limiting treatment options. This often results in severe, disabling disease. Recombinant uricases have been shown to have a very strong urate lowering potential.

Study objective

The primary outcome parameter is the Gout Activity Score (GAS)after 6 months of rasburicase treatment. Secondary outcome parameters are the serum uric acid concentration, the clinical evaluation of tophus load, patient reported outcomes: MD-HAQ, GAQ and safety measures (number of AE/SAEs), anti-drug antibody titers and to investigate B-cells response against Rasbirucase.

Study design

The study design is a proof of concept clinical pilot study in 20 patients with severe, tophaceous gout. All included patients will be treated with rasbirucase infusion for six months, with an additional follow up three months after last infusion or after discontinuation. Visits are scheduled monthly for infusion with Rasbirucase.

Intervention

All 20 included patients will be treated with monthly infusion of rasburicase, 0.20mg/kg intravenously for 6 months. To prevent infusion reactions/anaphylaxis, patients will receive 5mg levocetirizine po 2 hours before infusion and 100mg methylprednisolone iv concomitantly. In case of an infusion reaction or anaphylaxis, or a severe adverse event, treatment will be discontinued. There will be an observational follow-up period of 3 months after the last infusion.

Study burden and risks

The burden for participants will consist of the monthly infusion of rasburicase with pre-medication and associated diagnostic tests described in the section *Methods*. Despite administration of pre-medication and intensive monitoring of the participants at the day treatment facility a risk of infusion reaction or anaphylaxis to rasburicase exists. In previous investigations these have not been reported to be severe. However, before each administration anti-rasburicase antibodies as well as rasburicase trough level will be determined. In case of high antibody titers and unmeasurable rasburicase trough level, rasburicase administration will be discontinued for safety reasons to prevent an infusion reaction or anaphylaxis. In addition, there is a risk of (serious) adverse events or side effects to rasburicase. Finally, participants have an increased risk for gout flares, particularly in the 6 months period of monthly rasburicase administration, in spite of co-administration of methylprednisolone.

Contacts

Public
Jan van Breemen Instituut

Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB

NL
Scientific
Jan van Breemen Instituut

Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Adults (age >=18 years) with severe tophaceous gout not responding to standard treatment or contraindications to
standard treatment.
• Made the decision, along with their treating physician, to begin treatment with rasburicase
• Willing and able to give informed consent and adhere to visit/protocol schedules
• Written informed consent

Exclusion criteria

• Known glucose-6-phophate dehydrogenase deficiency or other cellular metabolic disorder causing hemolytic
anemia
• Recipient of an investigational drug within 4 weeks prior to study drug administration
• Non-compensated congestive heart failure
• Prior treatment with rasburicase or another recombinant uricase
• Pregnancy or breastfeeding

• Known allergy for rasburicase or added substances as described in the SmPC of Fasurtec

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Fasurtec
Generic name:	Rasburicase
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	22-03-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2024
Application type:	Amendment

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
EudraCT	EUCTR2020-002758-25-NL
CCMO	NL81601.018.22

Study results

Summary results
Trial never started