Rasburicase for gout

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27662

Source
Nationaal Trial Register

Brief title
RASGO

Health condition

Gout

Sponsors and support

Primary sponsor: Sanofi, Reade foundation
Source(s) of monetary or material Support: Sanofi, Reade foundation

Intervention

Outcome measures

Primary outcome

serum uric acid (mmol/l)

Secondary outcome

patient related outcomes, safety measures.

Study description

Background summary

The objective of the current investigation is to assess the efficacy and safety of rasburicase treatment in patients with severe gout. Patients will be treated with weekly infusion of rasburicase (0,15mg/kg) for 3 months. To prevent infusion reactions/anaphylaxis, patients will receive premadication (clemastine, methylprednisolon). The primary outcome is serum uric acid conentration after 3 months of treatment. Secondary outcomes will consist of a clinical evaluation of tophus load, patient reported outcome measures and safety measures.

Study objective

Treatment with rasburicase results in a decrease in serum uric acid and tophi.

Study design

3 months, 26 weeks

Intervention

rasburicase 0,15mg/kg, once a week during 3 months. Premedication: clemastine and methylprednisolon.

Contacts

Public
Reade
Daisy Vedder

0202421815
Scientific
Reade
Daisy Vedder

0202421815

Eligibility criteria

Inclusion criteria

Adults with severe tophaceous gout

Exclusion criteria

non-compensated congestive heart failure, prior treatment with a recombinant uricase, pregnancy, known allergy for rasburicase or added substances as described in the SmPC of Fasurtec. Known glucose-6-phosphate dehydrogenase deficiency or other cellular metabolic disorder causing hemolytic anemia. Recipient of an investigational drug within 4 weeks prior to study drug administration.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-05-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9180
Other	METC VUmc : to determined

Study results