Study to estimate the minimum clinically different difference in visual analogue scale scores for skin swelling, skin pain and abdominal pain in subjects with hereditary angio-edema

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The objective of the study is to estimate the utility and the minimally clinically significant symptom difference in VAS and verbal descriptor scores as the basis for the onset of relief for skin swelling, skin pain or abdominal pain in patients...

Ethical review	Approved WMO
Status	Pending
Health condition type	Immune system disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON30040

Source
ToetsingOnline

Brief title
VAS score angio-edema attack

Condition

- Immune system disorders congenital

Synonym
hereditairy angio-edema

Research involving
Human

Sponsors and support

Primary sponsor: Jerini AG
Source(s) of monetary or material Support: Jerini AG;Duitsland

Intervention

Keyword: C1-inhibitor, hereditary angio-edema

Outcome measures

Primary outcome

Descriptive research based on which the "minimally clinically significant

difference" in symptomscore can be assessed.

Secondary outcome

not applicable

Study description

Background summary

Hereditary angio-edema is a congenital disease due to a deficiency of C1-esterase inhibitor. It may lead to angio-edema attacks of various body parts, most commonly edema of arms, legs, facial area or genitals, abdominal attacks with severe pain or asphyxia due to edema in the laryngeal area. Recemtly new treatment modalities have been developed and for a proper clinical evaluation of these new options, a proper instrument for the interpretation of research results is required.

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Study objective

The objective of the study is to estimate the utility and the minimally clinically significant symptom difference in VAS and verbal descriptor scores as the basis for the onset of relief for skin swelling, skin pain or abdominal pain in patients with hereditary angio-edema experiencing an acute attack.

Study design

Patients will be asked to fill in sequential VAS scores and short questionnaires during an acute angio-edem attack (48 hrs).

Study burden and risks

The only burden is the recording of VAS scores and synmptom scores during 48 hrs after initiation of an angio-edema attack.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with documented type I or type II hereditary angio-edema (confirmed by medical history and C1-INH deficiency)

History of angio-edema attacks involving skin and/or abdomen
Male or Female
Age > 18 yrs
Signed written informed consent

Exclusion criteria

Diagnosis of angio-edema other than HAE, e.g. acquired angio-edema
Patients participating in other trials
Mental condition rendering the subject unable to understand the nature, scope, and possible consequences of the study
Patients unlikely to comply with protocol, e.g. uncooperative attitude, inability to return for follow-up, and unlikely to complete the study for any reason

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

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	NL13462.018.06