Adalimumab for the treatment of hs.

No registrations found.

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

Summary

ID

NL-OMON23669

Source
Nationaal Trial Register

Brief title
N/A

Health condition

hidradenitis suppurativa, acne inversa

Sponsors and support

Primary sponsor: Erasmus medical center Rotterdam
Source(s) of monetary or material Support: Abbott BV

Intervention

Outcome measures

Primary outcome

Primary outcome measure for the disease activity will be the modified Sartorius HS score.

Secondary outcome

DLQI quality of life form, Skindex-29 and a VAS pain score and a VAS patient disease global assessment score.

Study description

Background summary

Rationale:
Hidradenitis Suppurativa (HS) is a chronic inflammatory skin disease characterised by recurring painful abscesses and draining sinuses in the ano-genital-inguinal area and axillae, with a prevalence of 1%. The disease tends to be difficult to treat. TNF-alpha inhibitors have shown promising results in small groups of patients.

Primary Objective:
To determine the efficacy of clarithromycin plus adalimumab versus clarithromycin plus placebo adalimumab in patients with moderate to severe HS.

Secondary Objectives:

1. To determine the short-term side effects and tolerance of adalimumab for the treatment of HS;

2. To determine the duration of remission during follow-up. Defined as an increase of disease activity towards 50% or greater than the baseline HS score.

Study design:
Randomized double-blind single placebo controlled trial.

Study population:
Male/female patients older or 18 years of age with active, moderate to severe HS (Hurley stage 2 or Hurley stage 3)

Intervention:
The first group will receive current standard treatment or so called “gold standard” therapy in HS which is oral antibiotics by means of clarithromycin SR 1 gr a day orally and a placebo s.c. injection identical to adalimumab every other week for 6 months. A second group will receive clarithromycin SR 1 g a day orally and adalimumab s.c. 160 mg at week 0, 80 mg at week 2 and then every other week 40 mg for 6 months.

Main study parameters/endpoints:
The primary objective is to determine the efficacy of clarithromycin plus adalimumab versus clarithromycin plus placebo adalimumab in patients with moderate to severe HS (Hurley stage 2 or Hurley stage 3). Primary outcome measure for the disease activity will be the modified Sartorius HS score. In addition we will use the DLQI quality of life form, Skindex-29 and a VAS pain score and a VAS patient disease global assessment score. The outcome measures for the secondary objective are all side effects e.g. injection site reactions, infection rates, laboratory abnormalities, SAE’s and SUSARs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Participants will be seen in 18 visits in total. The screening comprises o.a. a chest x-ray, a Mantoux test and a serum pregnancy test (woman). Six blood samples will be obtained. Participants will be asked to fill in the DLQI, Skindex-29 and VAS scores 9 times. Pictures will be taken on 11 occasions and the blood pressure measured 4 times. At every visit a short medical exam will be done and patients will be asked about possible side effects.

Study objective

Adalimumab is a more effecient drug than oral claritromycin alone in the treatment of hidradenitis suppurativa.

Study design

0,5 year treatment and a 0,5 year follow-up.

Intervention

The first group will receive current standard treatment or so called “gold standard” therapy in HS which is oral antibiotics by means of clarithromycin SR 1 gr a day orally and a placebo s.c. injection identical to adalimumab every other week for 6 months. A second group will receive clarithromycin SR 1 g a day orally and adalimumab s.c. 160 mg at week 0, 80 mg at week 2 and then every other week 40 mg for 6 months.

Contacts

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Eligibility criteria

Inclusion criteria

Male/female patients older than 18 years of age with active moderate to severe hidradenitis suppurativa (Hurley stage 2 or Hurley stage 3).

Exclusion criteria

1. Subject has been treated with systemic corticosteroids (oral or parenteral) less than 4 weeks prior to baseline. Inhaled corticosteroids for stable medical conditions are allowed;

2. Subject has a poorly controlled medical condition, such as uncontrolled diabetes, unstable heart disease, recent cerebrovascular accidents, and any other condition, which in the opinion of the investigator, would put the subject at risk by participation in the study;

3. Subject has a history of clinically significant hematologic (e.g., severe anaemia, leukopenia, thrombocytopenia), renal, or liver disease (e.g., fibrosis, cirrhosis, hepatitis B or C), or NYHA class 3 or 4 congestive heart failure;

4. Subject has history of neurologic symptoms suggestive of CNS demyelinating disease and/or diagnosis of CNS demyelinating disease;

5. Subject has history of any cancer or lymphoproliferative disease;

6. Subject has a history of listeriosis, histoplasmosis, untreated or inadequately treated TB, persistent chronic infections, other than HS, or recent active infections requiring hospitalization or treatment with intravenous (IV) anti-infectives within 30 days or oral anti-infectives within 14 days prior to the 1st adalimumab dose;

7. Subject is known to have immune deficiency, history of HIV, or is immune compromised;

8. Female subject who is pregnant or breast-feeding or has positive serum pregnancy test at screening or considering becoming pregnant during the study or within 150 days after the last dose of Adalimumab;

9. Subject has a history of clinically significant drug or alcohol usage in the last year;

10. Known positive Hepatitis B or C serology indicative of previous or current infection;

11. Screening clinical laboratory analyses show any of the following abnormal hepatic laboratory results: Aspartate transaminase (AST) or alanine transaminase (ALT) > 2x the upper limit of normal (ULN). Serum total bilirubin more than 1.5 mg/dL (more than 26 micromol/L);

12. Subjects with known hypersensitivity to the constituents of study drugs (adalimumab, clarithromycin);

13. Subject who are previously treated with anti TNF-alpha.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	30
Type:	Anticipated

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	NL1652
NTR-old	NTR1750
Other	eudraCT : 2009-012138-57
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A