An independent prospective randomised controlled trial comparing the efficacy and cost effectiveness of infliximab and etanercept in 'high need' patients with moderate to severe chronic plaque type psoriasis

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What is the incremental cost effectiveness ratio of the use of etanercept versus infliximab?Are there subgroups of which infliximab or etanercept is more or less cost-effective in daily practice?Primary objectives: 1. To compare clinical efficacy of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Cornification and dystrophic skin disorders
Study type	Interventional

Summary

ID

NL-OMON35488

Source
ToetsingOnline

Brief title
Independent RCT comparing infliximab and enbrel in psoriasis. PIECE study

Condition

- Cornification and dystrophic skin disorders

Synonym
chronic skin disease with increased keratinization, psoriasis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Etanercept, Infliximab, psoriasis, Randomised controlled trial

Outcome measures

Primary outcome

Efficacy: - PASI75 and I-GA of clinical psoriasis severity of minimal or clear

at week 12 and 24.

-Improvement of HRQOL(Health related Quality of Life): median changes in the

three domain scores of the dermatology specific Skindex-17, the generic SF-36

and PAGA (patient global assessment).

-Treatment satisfaction: median changes Treatment Medication Satisfaction

Questionnaire (TMSQ) score.

- The incremental cost effectiveness ratio (ICER) of infliximab relative to

etanercept will be calculated and estimated in terms of costs per QALY (Quality

Adjusted Life Year), by using the EQ-5D.

- Nonmedical costs and medical cost outside the hospital will be assessing

using the Indirect medical costs questionnaire, and Labor and Health

Questionnaire.

Secondary outcome

- In (good-)responders, duration of remission (relapse of disease: 50% loss of

the obtained PASI improvement and/or need to retreat with UV and/or systemic

therapy including biologicals) will be analysed.

- In non-responders, patients perspectives of the comparative drug will be

analysed.

- Presence of neutralising antibodies will be measured to report if there is a

possible link to inefficacy.

- Side effects will be evaluated.

- The improvement of nailpsoriasis will be evaluated by the Nail Psoriasis

Severity index.

Study description

Background summary

TNF antagonists such as etanercept and infliximab (biologics) have been approved for the treatment of moderate to severe psoriasis patients. In the Netherlands etanercept is the most frequently prescribed biological. In comparison analysis it was suggested that infliximab is more effective than etanercept. However, the use of infliximab has several specific limitations. Costs associated with psoriasis care are considerable and are expected to increase steeply due to the introduction of the biologics. Furthermore psoriasis has an enormous impact on patients* health related quality of life (HRQOL).
There are no direct comparative studies available of infliximab and etanercept and existing studies did not include an economic evaluation of these expensive agents.
That*s why we want to compare by an independent prospective RCT the efficacy and cost effectiveness of infliximab and etanercept by these patients.

Study objective

What is the incremental cost effectiveness ratio of the use of etanercept versus infliximab?
Are there subgroups of which infliximab or etanercept is more or less cost-effective in daily practice?

Primary objectives:
1. To compare clinical efficacy of etanercept and infliximab (ie, proportion of

patients achieving PASI75, I-GA almost clear, clear).
2. To compare patient reported outcomes such as HRQOL and treatment satisfaction between etanercept and infliximab.
3. To compare from a societal perspective the incremental cost effectiveness ratio of the use of etanercept versus infliximab

Secondary objectives:
1. In (good-)responders, to compare the duration of remission.
2. In non-responders, to investigate patients perspectives of the comparative drug.
3. To compare the side-effects.
4. Subgroup analyses in relation to (cost-) effectiveness and safety, and antibody formation
5. To compare the improvement of nailpsoriasis graded by the NAPSI.

Study design

This trial is a multi-centre, pharmaceutical independent, prospective randomised controlled trial comparing head-to-head infliximab and etanercept.

Intervention

Treatment will be given according to nowadays standard care with respect to frequency of follow up and monitoring.
Etanercept will be self administered by subcutaneous injection between week 0 and 12 at a doses of 50 mg twice weekly (BIW). At week 12, patients with a PASI50 or more ((good-)responders) will continue 50 mg BIW for another 12 weeks up to week 24, non-responders (< PASI50) will switch to infliximab after a 4 week washout time.
Infliximab is an intravenous treatment with 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks thereafter. At week 12, (good-) responders (PASI50 or more) continue therapy with injections every other 8 weeks up to week 22, non-responders (< PASI50) switch to etanercept 50 mg BIW for 12 weeks.

At week 24 study treatment will be stopped, although there is a possibility to continue if the patient strongly insist of continuation, after informing them about the possible infusion reaction of infliximab retreatment .
If there is a PASI <50 after therapy stopped, (re-)treatment can be initiated at the outpatients'clinic. For infliximab retreatment this will be depending of the therapy free interval. Despite of the therapy, study follow up visits will be every two months up to one year.

Study burden and risks

A direct comparison of etanercept and infliximab is needed to answer which of these therapies is preferred by patients and which is the most cost-effective

drug in this subpopulation of psoriasis patients. The results of the study could help other psoriasis patients to get the best treatment of biologics.The benefit for the patient could be an improvement of the psoriasis plaques. The risks will be the same when prescribing biologics in regulary care, like infusion vs. injection site reactions, infections, malignancies and adverse events. These will be evaluated in the study. Recent developments suggests that retreatment of infliximab, after a therapy free period of more than 20 weeks, has a greater probability for infusion reactions.

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

- Adults patients (18-75 years of age)
- Psoriasis Area and Severity Index (PASI *10) and/or Body Surface Area (BSA) * 10, and/or

PASI* 8 together with skindex * 35.
- Failed, contraindicated and/or intolerant to UV therapy, en methotrexate or cyclosporin.
- Informed consent
- Able to complete Dutch questionnaires.

Exclusion criteria

- Pregnancy and lactation
- Active (or chronic) infections including Hepatitis B and C viral infections, HIV and tuberculosis
- Malignancy in last 10 years, except BCC and cervical in situ cancer
- Demyelinating disease
- Congestive heart failure
- Allergic and hypersensitivity reactions to study drugs or ingredients
- Any live virus or bacterial vaccination within 3 months
- Severe liverfunction disorders >2 times and/or kidney function disorders >1,5 times upper limits of the parameters.
-Treatment of infliximab or etanercept stopped because of inefficacy, contraindication or serious adverse events, after infliximab therapy for minimal 3 infusions and an evaluation after 12 weeks, or etanercept therapy for minimal 12 weeks

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Enbrel
Generic name:	Etanercept
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Remicade
Generic name:	Infliximab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-02-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-04-2009
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	EUCTR2008-007492-24-NL
CCMO	NL25795.018.09