An Open-Label Extension Study to Assess the Safety of GSK1605786A in Subjects with Crohn*s Disease (CCX114644)

Published: 09-11-2010
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Primary: Safety and tolerability. Secondary: Effectiveness, quality of life, healthcare resource utilisation, work productivity.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON36684

Source
ToetsingOnline

Brief title
CCX114644

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline BV

Intervention

Keyword: chemokine antagonist, Crohn's disease, GSK1605786A, longterm effects

Outcome measures

Primary outcome

Adverse effects.

Secondary outcome

Clinical response or remission, change in CDAI, IBDQ score, safety, quality of

life, healthcare related resource utilisation.

Study description

Background summary

GSK1605786A is an orally-administered chemokine antagonist which specifically blocks the migration of gut-specific T cells, which selectively home to the intestine.
Crohn*s disease is a chronic, idiopathic, relapsing inflammatory disorder of the gastrointestinal tract associated with a dysregulated activation of immune cell function. It can affect any portion of the gastrointestinal tract but most commonly affects the terminal small intestine and colon with patients experiencing considerable lifestyle disruption and disability including diarrhoea, abdominal pain, malnutrition and anaemia. Currently there is no curative medical therapy and patients may require treatment for life.
This study addresses primarily the longterm safety and tolerability of GSK1605786A (500 mg twice daily) in subjects with Crohn*s disease.

Study objective

Primary: Safety and tolerability. Secondary: Effectiveness, quality of life, healthcare resource utilisation, work productivity.

Study design

Multicenter open label non comparative phase III study.
Treatment with GSK1605786A 500 mg twice daily.
Plus background therapy (not part of study treatment, on prescription.
Treatment duration 2 years. Once the results of the induction study CCX114151

(see below) are known, the risk-to-benefit ratio will be re-assessed and the study may be extended to allow continued treatment up to the anticipated launch and availability of GSK1605786A.
Approx 800 patients.
Patients having participated in several preceding studies with GSK1605786A are eligible for this follow-up study.
This follow-up study has been submitted for approval at the same time. The same applies to the previous study CCX114151. For the Netherlands are of interest the induction study CCX114151 and the longterm efficacy study CCX114157. Both have a double blind randomized placebo controlled design. Two dosages of GSK1605786A are tested: 500 mg once and twice daily.
Subjects will enter the study via one of three routes: completion of the placebo-controlled induction study, CCX114151, without achieving clinical response or remission, completion of maintenance study CCX114157, withdrawal from maintenance study CCX114157 due to worsening of Crohn*s disease.

Intervention

Treatment with GSK1605786A.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: 23 visits in 2 years. Duration 0,5-1,5 h.
Blood tests 23x (approx.165 ml in total), pregnancy test (if relevant) 14x, ECG 6x. Questionnaires (EQ 5D, SF-36, IBDQ,WPI-CD) 4x.
Daily phone call to answer some questions about the abdominal symtoms during the 8 days preceding 11 visits Time consumption 5 min/day.

Contacts

Public
GlaxoSmithKline

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Completion of the placebo-controlled induction study, CCX114151, without achieving clinical response or remission or completion of maintenance study CCX114157, withdrawal from maintenance study CCX114157 due to worsening of Crohn*s disease.
* Safe contraception for women of childbearing potential.

Exclusion criteria

* Breastfeeding, pregnancy.
* Known coeliac disease, those who follow a gluten-free diet to manage symptoms of suspected coeliac disease and subjects with a positive screening test for celiac disease.
* Known or suspected small bowel stricture
* Enterocutaneous, abdominal or pelvic fistulae with abscesses or fistulae likely to require surgery during the study period.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	GSK1605786A
Generic name:	GSK1605786A

Ethics review

Approved WMO Date:	09-11-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2011
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
Other	clinicaltrials.gov, registratienummer n.n.b.
EudraCT	EUCTR2010-022384-35-NL
CCMO	NL34541.018.10