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

Published: 09-11-2010 Last updated: 04-05-2024

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

Huis ter Heideweg 62 3705 LZ Zeist NL

Scientific

GlaxoSmithKline

Huis ter Heideweg 62 3705 LZ Zeist NL

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

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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