A Phase I, Single-Centre, Randomized, Double-Blind, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability and Pharmacokinetics of CH-4051 in healthy male subjects

Published: 06-10-2008
Last updated: 06-05-2024

To evaluate the safety, tolerability and pharmacokinetics of ascending single and multiple doses of CH-4051.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON32763

Source
ToetsingOnline

Brief title
Single and Multiple Ascending Dose Study to Evaluate CH-4051.

Condition

- Autoimmune disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Chelsea Therapeutics, Inc.
Source(s) of monetary or material Support: Chelsea Therapeutics

Intervention

Keyword: Antifolate, CH-4051, pharmacokinetics, safety

Outcome measures

Primary outcome

Adverse events and tolerability

Secondary outcome

Pharmacokinetics

Study description

Background summary

CH-4051 is a new anti-folate study drug that inhibits folic acid in the human body. Folic acid is an important factor in DNA and protein synthesis. Folic acid is also involved in the production of red blood cells. Anti-folate medicines (eg, methotrexate) are effective against diseases of rapidly dividing cells and autoimmune diseases with inflammatory reactions, such as cancer, arthritis or psoriasis.

Folic acid / folate is an essential vitamin from the vitamin B complex. A human being can not produce folic acid or folates, and is thus dependent on the supply of food or food supplements. Sources of folate in the diet are green leafy vegetables, citrus fruit, yeast and some types of meat, especially liver. Folic acid is often present in fortified foods and dietary supplements (multi vitamin / mineral tablets).

Study objective

To evaluate the safety, tolerability and pharmacokinetics of ascending single and multiple doses of CH-4051.

Study design

Randomised, double-blind, placebo-controlled, single and multiple ascending doses

Study burden and risks

The risks during this trial are the possible side effects related to the study medication.
Also the admission period, venapunctures and placing the canula may cause a burden to the volunteers
Other assessments taking place during this trial: physical examination, vital signs, ECG, cardiac monitoring, blood and urine collection, drug screen, alcohol test and study restrictions.
All volunteers are being monitored by experienced physicians and study personell.

Contacts

Public
Chelsea Therapeutics, Inc.

3530 Toringdon Way, Suite 200
Charlotte, N.C. 28277
USA
Scientific
Chelsea Therapeutics, Inc.

3530 Toringdon Way, Suite 200
Charlotte, N.C. 28277
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

• written informed consent • males, 18-55 years of age • physically and mantally in good state of health • body mass index of 18-30 kg/m2 • no abnormalities found at screening

Exclusion criteria

• smoking or stopped smoking less than three months ago • drugs and/or alcohol abuse • drinking more than 21 glasses of alcohol per week • surgery in 3 months prior to study • hepatitis B, C or HIV positive • no history of infection with chicken pox • planning to be vaccinated with a (live) vaccine (yellow fever, MMR, and rubella) during the study • use of prescription medication within 4 weeks prior to the first dosing day • previously or currently receiving MTX • use of over-the-counter medication within 2 weeks prior to the first dosing day • vegetarians, vegans and/or having medical dietary restrictions • relevant food or drug hypersensitivity or allergy • having participated in an investigational drug study within 3 months prior to the dosing day • having donated blood within 12 weeks prior to the (first) dosing day • having a significant infection at screening • having an active viral, bacterial or fungal infection on day -1 • raised body temperature (>38 degrees celsius) on day -1 • taking co-trimoxazole or thrimethoprim • MCV > 95 fL • acute significant gastrointestinal symptoms on day -1 or prior to dosing on day 1.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2008

Enrollment:	56
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	CH-4051
Generic name:	CH-4051

Ethics review

Approved WMO Date:	06-10-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-10-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-11-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-11-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-02-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	26-02-2009

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-04-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2008-005524-85-NL
CCMO	NL24989.040.08