# A single-center, double-blind, randomized, placebo-controlled, 13-week study to evaluate the efficacy and safety of one capsule of XTEND-LIFE compared to placebo, and an extended four-week trial to assess its benefit when combined with ezetimibe 10 mg per day

| Submission date   | Recruitment status                | <ul><li>Prospectively registered</li></ul>    |
|-------------------|-----------------------------------|---|
| 23/03/2006        | No longer recruiting              | ☐ Protocol                                    |
| Registration date | Overall study status              | <ul><li>Statistical analysis plan</li></ul>   |
| 27/04/2006        | Completed                         | Results                                       |
| Last Edited       | Condition category                | Individual participant data                   |
| 02/05/2006        | Nutritional, Metabolic, Endocrine | <ul><li>Record updated in last year</li></ul> |

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

## Type(s)

Scientific

#### Contact name

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### Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

#### ClinicalTrials.gov number

#### Secondary identifying numbers

CCR-XL001

# Study information

#### Scientific Title

#### **Study objectives**

XTEND-LIFE treatment for 12 weeks results in significantly greater reduction in low-density lipoprotein (LDL-C) than treatment with placebo. The addition of ezetimibe further enhances the efficacy of XTEND-LIFE to lower LDL-C.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved by the Western Institutional Review Board (WIRB) on 29/09/2005, study number: 1069148, WIRB protocol number: 20051297

#### Study design

Randomized, double-blind, placebo-controlled study

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Hypercholesterolemia

#### **Interventions**

The study will compare 12 weeks of treatment with one capsule of XTEND-LIFE to placebo. After 12 weeks, ezetimibe 10 mg/day will be added.

#### Intervention Type

Drug

#### Phase

#### Drug/device/biological/vaccine name(s)

XTEND LIFE Capasule and ezetimibe

#### Primary outcome measure

To compare the low density lipoprotein cholesterol (LDL-C) lowering efficacy of XTEND-LIFE to placebo in patients with hypercholesterolemia

#### Secondary outcome measures

- 1. To evaluate the effect of XTEND-LIFE compared to placebo on total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglycerides, non-HDL-C, LDL-C:HDL-C ratio, apolipoprotein-B, apolipoprotein-A1, and high sensitivity C reactive protein
- 2. To evaluate the effect of XTEND-LIFE plus ezetimibe compared to ezetimibe and placebo on total cholesterol (TC), LDL-C, high density lipoprotein cholesterol (HDL-C), triglycerides, non-HDL-C, LDL-C:HDL-C ratio, apolipoprotein-B, apolipoprotein-A1, and high sensitivity C reactive protein
- 3. To explore the safety and tolerability of XTEND-LIFE with and without ezetimibe

#### Overall study start date

10/10/2005

#### Completion date

31/07/2006

# **Eligibility**

#### Key inclusion criteria

- 1. Men and women greater than 18 years of age with LDL-C greater than or equal to 130 mg/dl
- 2. Have not received any cholesterol lowering medication for 8 weeks
- 3. Patients with coronary heart disease or coronary heart disease risk equivalents and with documented intolerance or reluctance to take Hydroxamethylglutaryl-CoA (HMG-CoA) reductase inhibitors will be included, however, patients being treated with and who are tolerant of HMG-CoA reductase inhibitors will not be considered

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

60

#### Key exclusion criteria

- 1. Plasma triglycerides >400 mg/dl
- 2. Congestive Heart Failure (CHF) with New York Heart Association (NYHA) class 3 or 4
- 3. Hemoglobin A1C >9%
- 4. Ileal bypass or gastrointestinal (GI) disorder that can impair absorption of study drugs
- 5. Impaired renal function aspartate aminotransferase (AST) or alanine transaminase (ALT) >2 times the upper limit of normal
- 6. Uncontrolled endocrine disorder
- 7. Alcohol consumption >14 drinks per week
- 8. Lipid lowering medication within 8 weeks
- 9. Treatment with oral corticosteroids, immunosuppressants, androgens or warfarin

#### Date of first enrolment

10/10/2005

#### Date of final enrolment

31/07/2006

#### Locations

#### Countries of recruitment

United States of America

# Study participating centre 4675 Main Street

Bridgeport United States of America 06606

# Sponsor information

#### Organisation

Connecticut Clinical Research LLC (USA)

#### Sponsor details

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#### Sponsor type

Research organisation

# Funder(s)

**Funder type** Industry

Funder Name

Connecticut Clinical Research, LLC

# **Results and Publications**

**Publication and dissemination plan**Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration