

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomized, double-blind, placebo-controlled study

Study type(s)

Treatment

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

Not Specified

Drug/device/biological/vaccine name(s)

XTEND LIFE Capasule and ezetimibe

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

Funder(s)

Funder type

Industry

Funder Name

Connecticut Clinical Research, LLC

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration