ISRCTN36282240 https://doi.org/10.1186/ISRCTN36282240

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

Registration date
27/04/2006

Last Edited
02/05/2006

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] 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

Contact name
Dr Edward Kosinski

Contact details
4675 Main Street
Bridgeport
United States of America
06606
+1 203 683 5111
edward_kosinski@med3000.com

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

Not Specified

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
4675 Main Street
Bridgeport
United States of America
06606
+1 203 683 5130
maria_capasso@med3000.com

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