ISRCTN64317949 https://doi.org/10.1186/ISRCTN64317949

A phase 1, randomized, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetic profiles of OLX10010 in healthy subjects compared to placebo

Submission date
15/05/2018

Recruitment status
No longer recruiting

Registration date
18/05/2018

Overall study status
Completed

Last Edited
08/08/2019

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The study drug (OLX10010) is an investigational drug which is being developed by OliX Pharmaceuticals Inc., with the aim to help people who develop hypertrophic scars (a type of permanent scar) in the future. Hypertrophic scars are formed when a wound becomes red, raised, and itchy before it eventually heals. These scars tend to develop due to disease, surgical operations, or burns. There are an estimated 92 million patients in the US who have developed these scars, and this number is expected to continue to rise. In the UK it is reported by the British Skin Foundation that seven in ten people have visible scars or skin conditions, and of these people, 72% say that it affects their confidence. Research by 'Changing Faces' has also shown that 1,345,000 people (1 in 44 people) have a significant disfigurement to their face or body. There are currently no therapeutic drugs or methods that allow for the complete prevention or treatment of hypertrophic scars. Available physical treatment methods to remove scars include surgery or laser therapy, but these are often accompanied by further complications including pain and recurrence of the scar and can be costly. Similarly, treatments such as ointments or oral drugs have little to no effect in preventing or treating hypertrophic scars. The aims of this study are to determine the safety of the study drug and any side effects that might be associated with it, and how much of the study drug gets into the bloodstream and how long it takes the body to remove it.

Who can participate?
Healthy volunteers aged 18 to 60 years old (women In Groups A1 to A4 must be postmenopausal or have had a hysterectomy)

What does the study involve?
This study is conducted in two parts, Part A and B. In Part A, 32 participants are randomly allocated into eight groups (A1 to A8). In each of Groups A1 to A8, three participants receive OLX10010 and one participant receives a placebo (dummy drug). Groups A1 to A4 are injected subcutaneously (into the fatty layer of tissue under the skin) at a single injection site. Groups A5

to A8 are injected intradermally (into the dermis skin layer) and the doses are given at different dose volumes at either two or four injection sites. Each participant participates in one treatment period only and stays at the Clinical Research Unit (CRU) from Day -1 (the day before dosing) to Day 3 (48 hours after dosing). Participants return for a follow-up visit at 14±2 days after dosing. All groups are divided into two cohorts, with each cohort being dosed at least 24 hours apart. The first cohort comprises two participants, one of whom receives OLX10010 and one of whom receives placebo. The second cohort comprises two participants who both receive OLX10010. There is minimum of 2 weeks between dose increases to allow enough time for a safety review. In Part B, 12 participants are randomly allocated into three groups (Groups B1 to B3) with each group consisting of four participants. In each group, three participants receive OLX10010 and one participant receives a placebo. Each participant is given three doses of OLX10010 or placebo at 2-week intervals (i.e., on the morning of Days 1, 15, and 29). Participants stay at the CRU from Days -1, 14, and 28 (i.e., the day before dosing) until Days 3, 17, and 31 (i.e., 48 hours after each dose). Participants return for a follow-up visit at 14±2 days after their final dose. The dose given at each occasion does not exceed the highest well-tolerated single dose in Part A. There is a minimum of 2 weeks between dose increases to allow enough time for a safety review.

What are the possible benefits and risks of participating?
Participants do not receive any health benefit (beyond that of an assessment of their medical status). The risks of participation are side effects such as injection site pain and reactions, although there may also be some discomfort from collection of blood samples and other study procedures.

Where is the study run from?
Covance Clinical Research Unit (UK)

When is the study starting and how long is it expected to run for?
January 2018 to May 2019

Who is funding the study?
OliX Pharmaceuticals, Inc. (South Korea)

Who is the main contact?
Mr David Lee

Contact information

Type(s)
Public

Contact name
Mr David Lee

Contact details
1014, Gwanggyo Ace Tower 1
17, Daehak 4 ro
Yeongtong gu
Suwon City
Korea, South
16226

Additional identifiers

EudraCT/CTIS number
2017-001675-23

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OLX10010-01

Study information

Scientific Title
A phase 1, single center, placebo-controlled, interventional study to evaluate the safety, tolerability, and pharmacokinetic profiles in healthy subjects compared to placebo

Study objectives
The aim of this study is to evaluate the safety, tolerability, and pharmacokinetic profiles of OLX10010 single and multiple doses compared to placebo in healthy subjects.

Hypothesis: OLX10010 is a safe drug for healthy adult subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - York Research Ethics Committee, 23/04/2018, ref: 17/NE/0125

Study design
Phase I single-center interventional partially- (Part A) and double-blind (Part B) placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healthy subjects without significant conditions

Interventions
This study will be conducted in 2 parts, Part A and B.

Part A will be a single subcutaneous dose (Groups A1 to A4) or intradermal dose (Groups A5 to A8), dummy controlled study. Overall, 32 subjects will be studied in 8 groups; 4 groups (Groups A1 to A4) of 4 subjects to assess OLX10010 administered subcutaneously and 4 groups (Groups A5 to A8) of 4 subjects to assess OLX10010 administered intradermally. In Groups A1 to A4, doses will be administered at a single injection site. In Groups A5 to A8, the doses will be administered at different dose volumes at either 2 or 4 injection sites. In each of Groups A1 to A8, 3 subjects will receive OLX10010 and 1 subject will receive placebo. Each subject will participate in 1 treatment period only and reside at the Clinical Research Unit (CRU) from Day -1 (the day before dosing) to Day 3 (48 hours postdose). Subjects will return for a Follow-up Visit at 14±2 days postdose. All groups will be divided into 2 cohorts, with each cohort being dosed at least 24 hours apart. The first cohort will comprise 2 subjects, 1 of whom will receive OLX10010 and 1 of whom will receive placebo. The second cohort will comprise 2 subjects; both subjects will receive OLX10010. All groups will therefore be only partially-blinded. There will be a minimum of 2 weeks between dose escalations to allow sufficient time for an adequate safety review.

A1: 1 mg of OLX10010 or placebo, subcutaneously
A2: 4 mg of OLX10010 or placebo, subcutaneously
A3: 10 mg of OLX10010 or placebo, subcutaneously
A4: 20 mg of OLX10010 or placebo, subcutaneously
A5: 4 mg of OLX10010 or placebo, intradermally (4 injection sites)
A6: 10 mg of OLX10010 or placebo, intradermally (4 injection sites)
A7: 10 mg of OLX10010 or placebo, intradermally (2 injection sites)
A8: 20 mg of OLX10010 or placebo, intradermally (4 injection sites)

Part B will be a multiple intradermal dose, dummy controlled study. Overall, 12 subjects will be studied as 3 groups (Groups B1 to B3) with each group consisting of 4 subjects. In each group, 3 subjects will receive OLX10010 and 1 subject will receive placebo. Each subject will be given 3 dose administrations of OLX10010 or placebo at 2 week intervals (i.e., on the morning of Days 1, 15, and 29). Subjects will reside at the CRU from Days -1, 14, and 28 (ie, the day before dosing, respectively) until Days 3, 17, and 31 (ie, 48 hours postdose of each dose, respectively). Subjects will return for a Follow-up Visit at 14±2 days after their final dose. The dose administered at each dosing occasion will not exceed the highest well-tolerated single dose in Part A. There will be a minimum of 2 weeks between dose escalations to allow sufficient time for an adequate safety review.

B1: OLX10010 or placebo biweekly for 3 times, intradermally (dose will be determined after Part A)
B2: OLX10010 or placebo biweekly for 3 times, intradermally (dose will be determined after Part A)
B3: OLX10010 or placebo biweekly for 3 times, intradermally (dose will be determined after Part A)

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
OLX10010

Primary outcome measure
Safety and tolerability of single subcutaneous and intradermal doses, and multiple intradermal doses of OLX10010. Safety and tolerability are evaluated by adverse events upon checking clinical symptoms, lab values, injection site tolerability, and so on. Single dose ascending groups will be monitored at Day 14. Multiple dose ascending groups will be treated with OLX10010 or placebo 3 times on Day 1, 15, and 29, and their safety profiles are monitored up to Day 43.

Secondary outcome measures
Pharmacokinetics of OLX10010 will be evaluated. The blood samples are collected at predose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 36, and 48 hours postdose.

Overall study start date
17/01/2018

Completion date
27/06/2019

Eligibility

Key inclusion criteria
1. Males or females, of any race, between 18 and 60 years of age, inclusive, at Screening. For Groups A1 to A4 only, females must be postmenopausal or have had a hysterectomy
2. Body mass index (BMI) between 18.0 and 32.0 kg/m2, inclusive, at Screening
3. In good health, determined by no clinically significant findings from medical history, physical examination, 12-lead ECG, vital sign measurements, and clinical laboratory evaluations (congenital non-haemolytic hyperbilirubinaemia [e.g., Gilbert’s syndrome] is not acceptable) at Screening and/or Check-in as assessed by the Investigator (or designee)
4. Female subjects will be non-pregnant and non-lactating
5. Able to comprehend and willing to sign an ICF and to abide by the study restrictions

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
44

Key exclusion criteria

1. Male subjects who do not agree, or whose partners of childbearing potential do not agree, to use a male barrier method of contraception (i.e., a male condom with spermicide) in addition to a second method of acceptable contraception used by their female partners or to refrain from donating sperm from Check-in until 90 days after the Follow-up Visit
2. Female subjects of childbearing potential who do not agree to use a highly effective method of birth control in conjunction with male barrier method contraception (i.e., a male condom with spermicide) or to refrain from donating ova from the time of signing the ICF until 90 days after the Follow-up Visit. a. For Groups A1 to A4 only, females must be postmenopausal or have had a hysterectomy
3. Significant history or clinical manifestation of any metabolic, allergic, dermatological, hepatic, renal, haematological, pulmonary, cardiovascular, gastrointestinal, neurological, respiratory, endocrine, or psychiatric disorder, as determined by the Investigator (or designee)
4. Subjects with serum creatinine >ULN
5. History of significant hypersensitivity, intolerance, or allergy to any drug compound, food, or other substance, unless approved by the Investigator (or designee)
6. History of alcoholism or drug/chemical abuse within 2 years prior to Check-in
7. Alcohol consumption of >28 units per week for males and >21 units for females. One unit of alcohol equals ½ pint (285 mL) of beer or lager, 1 glass (125 mL) of wine, or 1/6 gill (25 mL) of spirits
8. Positive alcohol breath test result or positive urine drug screen (confirmed by repeat) at Screening and/or Check-in
9. Positive hepatitis panel and/or positive human immunodeficiency test at Screening. Subjects whose results are compatible with prior immunisation and not infection may be included at the discretion of the Investigator
10. Participation in a clinical study involving administration of an investigational drug (new chemical entity) in the past 3 months (or 5 half-lives, whichever is longer) prior to Check-in
11. Excessive consumption of food or drink containing caffeine, including coffee, tea, cola, energy drinks, or chocolates (>8 cups of coffee or equivalent per day)
12. Consumption of food or drinks containing poppy seeds, grapefruit, or Seville oranges from 7 days prior to Screening
13. Use, or intend to use, any prescription medications/products other than oral, implantable, transdermal, injectable, or intrauterine contraceptives, or hormone replacement therapy, within 14 days prior to Check-in, unless deemed acceptable by the Investigator (or designee)
14. Use, or intend to use, slow-release medications/products considered to still be active within 14 days prior to Check-in, unless deemed acceptable by the Investigator (or designee)
15. Use, or intend to use, any non-prescription medications/products including vitamins, minerals, and phytotherapeutic/herbal/plant-derived preparations within 7 days prior to Check-in, unless deemed acceptable by the Investigator (or designee)
16. Use of tobacco- or nicotine-containing products within 3 months prior to Check-in
17. Receipt of blood products within 2 months prior to Check-in
18. Donation of blood from 3 months prior to Screening, plasma from 2 weeks prior to Screening, or platelets from 6 weeks prior to Screening
19. Poor peripheral venous access
20. Subjects who have tattoos, scars, or moles, that in the opinion of the Investigator are likely to interfere with dosing or study assessments at any of the potential injection sites (abdomen)

Date of first enrolment

21/05/2018

Date of final enrolment

17/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Covance Clinical Research Unit (CRU) Ltd.
Springfield House
Hyde Street
Leeds
United Kingdom
LS2 9LH

Sponsor information

Organisation
OliX Pharmaceuticals, Inc.

Sponsor details
1014, Gwanggyo Ace Tower 1
17, Daehak 4 ro
Yeongtong gu
Suwon City
Korea, South
16226

Sponsor type
Industry

Website
www.olixpharma.com

Funder(s)

Funder type
Industry

Funder Name

OliX Pharmaceuticals, Inc.

Results and Publications

Publication and dissemination plan
Not planned yet

Intention to publish date

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No