ISRCTN13034712 https://doi.org/10.1186/ISRCTN13034712

Safety evaluation of low-level chlorine in water aerosol when inhaled by healthy volunteers

Submission date
03/12/2021

Recruitment status
No longer recruiting

Registration date
15/12/2021

Overall study status
Completed

Last Edited
15/12/2021

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims.
Human white blood cells produce aqueous (dissolved) chlorine that has been reproduced as HS4-20 and used to prevent wound infection and inflammation when administered to the skin and other surfaces. It is believed that this would be beneficial when administered to the airways and lungs to treat lung and airway diseases. The study is designed to discover if HS4-20 is safe to administer as an aerosol and breathe. The study is designed to begin at a short exposure of 30 seconds and, if safe to do so, increase exposure to 90 minutes over several days and in up to 18 healthy volunteers.

Who can participate?
Healthy volunteers

What does the study involve?
The participants breathe in aerosolised HS4-20 over several days and escalating from 30 seconds to 90 minutes.

What are the possible benefits and risks of participating?
There are no expected benefits. The possible risk of participation is increased expectoration (spitting) or mild coughing

Where is the study run from?
Hypo-Stream (UK)

When is the study starting and how long is it expected to run for?
May 2015 to September 2020.

Who is funding the study?
Hypo-Stream Ltd (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HS4-20 SE

Study information

Scientific Title
Open-label, exposure-escalation study to evaluate the safety and tolerability of nebulised HS4-20 in healthy volunteers

Acronym
SEHS4-20

Study objectives
That inhalation of HS4-20 via a nebuliser is is safe and without adverse events over long periods of time.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics approval not required. An open-label, exposure escalation study was planned following a safety evaluation via formal scientific advice from the HMRA and subsequent formal scientific advice from the EMA. The study was planned and directed by Prof. R Aspinall (translational medicine) and Dr Thomas Kenny (formerly director at NIHR).

Study design
Open-label exposure-escalation study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Safety evaluation of nebulised HS4-20 physiologic aqueous chlorine aerosol

Interventions
Pulmonary administration of HS4-20 as an aerosol via a nebuliser.

The healthy volunteers were divided into three cohorts:
1. Two adults. Exposure escalation from 30 seconds increasing to 30 minutes. A subsequent day exposure escalation from 5 minutes escalating to 90 minutes.
2. Four adults. Exposure escalation from 30 seconds to 20 minutes. Subsequent day exposure for 20 minutes repeated twice.
3. 12 adults and children. An induction phase of 5 minutes escalating to 20 minutes. Subsequent day exposure of 20 minutes.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
HS4-20

Primary outcome measure

Treatment-emergent adverse events measured using observation for the absence of abnormality and of coordination by a clinically trained investigator over a 30-minute period following administration. Follow-up was 7 days post-administration self-reporting. The final follow-up was over a 12-month period of self-reporting and investigator interview.

Secondary outcome measures
1. Blood pressure measured with an automatic upper arm cuff sphygmomanometer (Omron X3) at baseline (pre-administration), 30 seconds, 2, 5, 10, 20, 30 minutes post-administration in first and second cohorts, the third cohort was measured at 30 seconds, 5, 20, 30 minutes
2. Oxygen saturation measured by pulse oximeter (Braun Healthcare Pulse Oximeter 1) throughout the periods of exposure and for 30 minutes after cessation of administration

Overall study start date
02/05/2015

Completion date
20/09/2020

Eligibility

Key inclusion criteria
Healthy volunteers, no exclusions on basis of age or gender

Participant type(s)
Healthy volunteer

Age group
All

Sex
Both

Target number of participants
18

Total final enrolment
18

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/06/2015

Date of final enrolment
20/09/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hypo-Stream Ltd
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Sponsor information

Organisation
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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Hypo-Stream Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal from the Nature group.

Intention to publish date
02/02/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0		09/12/2021	No	Yes
Protocol file			09/12/2021	No	No