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First-in-human study of Sirona: a study to determine safety, feasibility, and tolerability of an expanding hydrogel tablet designed to promote weight loss in adults with a body mass index of 30-40 kg/m²

Submission date
16/03/2022

Recruitment status
No longer recruiting

Registration date
18/05/2022

Overall study status
Completed

Last Edited
16/04/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Obesity is the most serious public health problem in the UK and the developed world, and the second most common cause of cancer. It is responsible for 80% of type 2 diabetes and 30 to 90% of people with non-alcoholic fatty liver disease (NAFLD) are obese. Furthermore, there is a 33% increased risk of death from COVID-19 if the individual is obese. Obesity has a serious impact on the economy and its development; 52% of adults worldwide are overweight or obese, costing the global economy $2 trillion every year. People with obesity have a reduced quality of life (QOL) and a reduced life span. Obesity is a complex disease and the factors that control weight are multifaceted. People with excess weight currently have three options: diet and exercise, medical treatment, or surgery. There is an urgent need for a safe, effective, and affordable therapy to aid weight loss. A safe, cost-effective solution would allow clinicians to intervene earlier, aiding both weight loss and preventing progression to a higher class of obesity.

Hydrogels have received considerable attention in the past 50 years due to their exceptional promise in a wide range of applications. Hydrogels are biochemically inert and have a well-established role in everyday products such as contact lenses, hygiene products, tissue engineering scaffolds, drug delivery systems and wound dressings. Many hydrogel-based drug delivery and scaffolds have been designed, studied and in some cases even patented. Oxford Medical Products (OMP) have developed Sirona, which is designed to be a safe, effective and affordable approach to weight loss that uses a self-expanding hydrogel that occupies space in the stomach and has the potential to reduce hunger and appetite, leading to changes in eating behaviour and subsequent weight loss. This study aims to determine the safety, feasibility and tolerability of Sirona (hydrogel) as a potential non-surgical, non-pharmaceutical intervention to support weight loss.

Who can participate?
Adults aged 18-65 years with a BMI between 30 and 40 kg/m²

What does the study involve?
The study will be split into two work packages, WP1 and WP2.
WP1 will focus on the safety, feasibility and tolerability of product use. This will be undertaken at Southampton Hospital only. The sponsor will ensure one participant is dosed initially to ensure safety parameters are maintained. If there are no reported serious adverse events (SAEs) related to Sirona by study day 7, the following two participants will be dosed. Again, safety data will be reviewed up to day 7 and if there are no reported SAEs related to Sirona, the remaining seven participants will be dosed. Each participant will undergo two dosing cycles (each dosing cycle a 28-day cycle). Dosing cycle 1 (days 1-3) and dosing cycle 2 (days 1) will be undertaken in hospital (outpatients), with dosing cycle 2 days 2-4 undertaken at home observed by a research nurse via Zoom for WP1. Each participant will take two tablets per day aiming for a total of six tablets (achieving a 250 ml hydrogel expansion) in dosing cycle 1 and three tablets per day aiming for a total of 12 tablets (achieving a 500 ml hydrogel expansion) in dosing cycle 2. All safety data (up to day 28 following the last participant's cycle 2) will be reviewed by the safety monitors. The outcome of product use and safety will be used to determine the number of tablets and dosing frequency required for WP2. Approval from the safety monitors will be required before proceeding to WP2.

WP2 will focus on the safety, feasibility and tolerability of product use, along with secondary objectives evaluating weight, weight circumference and BMI changes, changes in glucose and HbA1c levels, changes in metabolomics, micronutrients, appetite and participant's experiences. WP2 will be undertaken in Southampton and Bristol Hospitals.

WP2 is comprised of two 12-week periods: (1) Daily dosing with either Sirona or a placebo pill and (2) daily dosing with Sirona for all participants. Over the first month, the dose will gradually increase from 1 pill every other day to 2 pills a day to allow patients to find their ideal tolerated dose, with the support of the clinical research team. Each participant will be monitored and adjustments made for dosing (if required) by the Principal Investigator based on participant feedback and clinical parameters. Any dose adjustment will be recorded along with reasons for adjustment.

Safety will be assessed through close monitoring of serious adverse events, gastroscopy, MRI and key blood and stool parameters. Feasibility will be assessed through measures of recruitment and adherence to protocol requirements. Tolerability will be assessed through participant experience questionnaires.
Secondary measures (WP2) will include changes in subjective appetite ratings, weight, Body Mass Index (BMI), blood glucose levels and HbA1c levels, along with other metabolomics and micronutrient samples.

What are the possible benefits and risks of participating?
Participants may experience weight loss by taking part in this study. However, there is no guarantee that Sirona will directly benefit participants. Participation may help others as information learned from this study will be used in future to plan the next part of this study and future studies to benefit other people with obesity.
Participants may experience some side effects after consuming Sirona. At this stage, the exact side effects in humans are not known. This study will be looking at this aspect. Based on their clinical experience, the study team suggest that the side effects may be similar to having a gastric balloon (including mild nausea for the first 24-48 following dosing, bloating, and indigestion). Participants must tell their doctor or nurse if they experience any effects after

taking Sirona. They will suggest ways to make them more comfortable. Participants will need to attend several clinics and MRI appointments. They will need to have regular blood tests (may experience mild discomfort, such as bruising and tenderness) and a gastroscopy. Some people feel anxious inside an MRI scanner, and it can be noisy. The researchers will provide earplugs and make participants as comfortable as possible. Participants will need to attend their hospital appointments fasted (not eating or drinking calorie-containing drinks from midnight the night before their appointments). Alcohol consumption should not affect the function of the Sirona tablets, although it may cause heartburn and indigestion. The researchers advise either abstinence from alcohol or consumption in moderation during the study. It is important not to exceed the dosage of Sirona given by the study team. There is a potential risk with taking too many tablets (e.g. danger of uncomfortable swelling or rupture of the stomach).

Where is the study run from?
Oxford Medical Products (OMP) (UK)

When is the study starting and how long is it expected to run for?
January 2022 to January 2025

Who is funding the study?
Oxford Medical Products (OMP) (UK)

Who is the main contact?
Pharmexcel CRO and Elanor Hinton (Clinical Studies Manager)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307759

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
RDD-022, IRAS 307759, CPMS 51908

Study information

Scientific Title
First-in-human study of Sirona, an expanding hydrogel tablet, designed to promote weight loss in humans: a study to determine safety, acceptability to the participant, retention of hydrogels in the stomach through MRI study, dosing in healthy subjects with a body mass index of 30-40 kg /m², and impact on appetite and eating behavior

Acronym
SIRONA

Study objectives
Sirona is a safe and well-tolerated slimming aid that helps to modulate users' appetite and hunger as well as aiding weight loss.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/05/2022, South Central - Hampshire B Research Ethics (2 The Square, Temple Quay, Temple Quay House, Bristol, BS1 6PN, United Kingdom; +44 0207 1048 088; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0081

Study design
Multi-centre interventional study incorporating a 12-week double-blind placebo-controlled randomized phase

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Prevention of excessive weight and obesity

Interventions

Current interventions as of 23/02/2024:
This is a multi-centre, interventional study evaluating the safety, feasibility and tolerability of Sirona hydrogel on a population of healthy male and female adults with a BMI of 30-40 kg/m². The study will be split into two work packages WP1 and WP2. Data will be collected throughout the study to evaluate the primary and secondary objectives.

WP1 will be undertaken in 10 participants and will focus on the safety, feasibility and tolerability of product use. This will be undertaken at Southampton Hospital only. The sponsor will ensure one participant is dosed initially to ensure safety parameters are maintained. If there are no reported serious adverse events (SAEs) related to Sirona by study day 7, the following two participants will be dosed. Again, safety data will be reviewed up to day 7 and if there are no reported SAEs (related to Sirona), the remaining seven participants will be dosed.

Each participant will undergo two dosing cycles (each dosing cycle a 28-day cycle). Dosing cycle 1 (days 1-3) and dosing cycle 2 (days 1), will be undertaken in hospital (outpatients), with dosing cycle 2 days 2-4 undertaken at home observed by a research nurse via zoom for WP1.

Each participant will take two tablets per day aiming for total of six tablets (achieving a 250 ml hydrogel expansion) in dosing cycle 1 and three tablets per day aiming for a total of 12 tablets (achieving a 500 ml hydrogel expansion) in dosing cycle 2.

All safety data (up to day 28 following the last participant's cycle 2) will be reviewed by the safety monitors. The outcome of product use and safety will be used to determine the number of tablets and dosing frequency required for WP2; however, the researchers anticipate that the higher dosing of 12 tablets will be followed. Approval from the safety monitors will be required before proceeding to WP2.

WP2 will be undertaken in 40 participants and will focus on the safety, feasibility and tolerability of product use, along with secondary objectives evaluating weight, weight circumference and BMI changes, changes in glucose and HbA1c levels, changes in metabolomics, micronutrients, appetite and participant's experiences. WP2 will be undertaken in Southampton and Bristol Hospitals.

WP2 will comprise two 12-week periods: (1) a double-blind, placebo-controlled trial of daily dosing (with an initial dose-escalation period for safety and tolerability assessment), (2) an extension period in which all participants will receive daily dosing of Sirona in an open-label design, either continuing with Sirona (Sirona arm) or start taking Sirona (Ex-placebo arm).

Participants will be allocated to one of two treatments: Sirona or a placebo pill as a sham treatment. The term 'treatment' has been used here and throughout this document to be in line with usual terminology for double-blind randomised trials, but it is noted that Sirona is a slimming aid and not classed as a treatment for obesity in the UK. As described elsewhere, Sirona is based on a uniquely processed, hydrogel co-polymer which swells on contact with water or gastric fluid to up to 20 times its original volume. The expanded hydrogel may occupy up to 25 - 50% volume in the stomach for 2-5 days. The density of the swollen hydrogel is less than that of water, enabling it to float at the top of the stomach contents exerting pressure on the stomach walls, stimulating the vagus nerve which leads to a feeling of fullness.

The placebo pills will be supplied by Zeebo Effect LLc and will consist of microcrystalline cellulose (96%) with a coating comprised of magnesium stearate and silica. Microcrystalline cellulose (E460(i)) is a plant fibre with no nutritional value. This ingredient is known to be safe

for ingestion and has been used in placebo pills as provided by Zeebo Effect previously. Magnesium stearate (E470b) and silica (E551) are recognised by the FDA to be safe for consumption. The placebo pills will be the same size, colour and shape and be of a similar weight to the Sirona tablets.

For the first 12-week trial period, participants will be randomised to one of two arms: Sirona arm (approx. n=30) or Placebo arm (approx. n=10). Due to the small sample size, stratification of participants based on factors such as site, sex or baseline BMI will not be feasible, therefore a simple blocked random allocation sequence will be computer-generated such that participants are randomly assigned in a 3:1 ratio across the whole study (not stratified by site). The randomisation schedule will be created within the Electronic Data Capture (EDC) system. The randomisation will be conducted during enrolment as each participant's eligibility is confirmed in the EDC. Upon eligibility confirmation, the EDC will automatically assign each participant with an encrypted code, which will be emailed to the unblinded team to decode for the participant's treatment allocation, using a list provided by the database team

Previous Interventions:
This is a multi-centre, interventional study evaluating the safety, feasibility and tolerability of Sirona hydrogel on a population of healthy male and female adults with a BMI of 30-40 kg/m^2. The study will be split into two work packages WP1 and WP2. Data will be collected throughout the study to evaluate the primary and secondary objectives.

WP1 will be undertaken in 10 participants and will focus on the safety, feasibility and tolerability of product use. This will be undertaken at Southampton Hospital only. The sponsor will ensure one participant is dosed initially to ensure safety parameters are maintained. If there are no reported serious adverse events (SAEs) related to Sirona by study day 7, the following two participants will be dosed. Again, safety data will be reviewed up to day 7 and if there are no reported SAEs (related to Sirona), the remaining seven participants will be dosed.

Each participant will undergo two dosing cycles (each dosing cycle a 28-day cycle). Dosing cycle 1 (days 1-3) and dosing cycle 2 (days 1), will be undertaken in hospital (outpatients), with dosing cycle 2 days 2-4 undertaken at home observed by a research nurse via zoom for WP1.

Each participant will take two tablets per day aiming for total of six tablets (achieving a 250 ml hydrogel expansion) in dosing cycle 1 and three tablets per day aiming for a total of 12 tablets (achieving a 500 ml hydrogel expansion) in dosing cycle 2.

All safety data (up to day 28 following the last participant's cycle 2) will be reviewed by the safety monitors. The outcome of product use and safety will be used to determine the number of tablets and dosing frequency required for WP2; however, the researchers anticipate that the higher dosing of 12 tablets will be followed. Approval from the safety monitors will be required before proceeding to WP2.

WP2 will be undertaken in 36 participants and will focus on the safety, feasibility and tolerability of product use, along with secondary objectives evaluating weight, weight circumference and BMI changes, changes in glucose and HbA1c levels, changes in metabolomics, micronutrients, appetite and participant's experiences. WP2 will be undertaken in Southampton and Bristol Hospitals.

Each participant will undergo six dosing cycles (each period a 28-day cycle). Day 1 dosing of cycles 1 and 4 will be undertaken in hospital (outpatients). All other dosing will be undertaken at home observed by a research nurse via zoom. WP2 will aim for each participant to take three

tablets per day (days 1-4) in each cycle (achieving and maintaining 500 ml hydrogel expansion at each cycle). Each participant will be monitored and adjustments made for dosing (if required) by the Principal Investigator based on participant feedback and clinical parameters. Any dose adjustment will be recorded along with reasons for adjustment.

Intervention Type
Other

Primary outcome measure
WP0:
1. The total number of reported Serious Adverse Events (SAEs) measured using throughout the study. All AEs observed by the Investigator or reported by the participant, whether or not attributed to Sirona, will be recorded in the eCRF by the study team with a full description including the nature, date and time of onset, determination of non-serious versus serious, severity (grades 1-5), causality (unrelated possibly, probably or related), and outcome of the event. AE data will be made available to the Chief Investigator (or designee) and the safety reviewers. Serious Adverse Event (SAE): an SAE is any adverse intervention experience occurring at any dose that results in any of the following outcomes:
1.1. Death
1.2. A life-threatening event (at risk of death at the time of the event)
1.3. Requires inpatient hospitalization or prolongation of existing hospitalization
1.4. A persistent or significant disability/incapacity, or
1.5. A congenital anomaly/birth defect in the offspring of a subject.
Important medical events that may not result in death, be life-threatening, or require hospitalisation may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
A distinction should be drawn between serious and severe AEs. A severe AE is a major event of its type. A severe AE does not necessarily need to be considered serious. For example, nausea which persists for several hours may be considered severe nausea but would not be an SAE. On the other hand, a stroke that results in a limited degree of disability may be considered a mild stroke, but would be an SAE as meets the definition of serious (above).
2. Gastric transit time of Sirona, determined by MRI reflecting the retention of hydrogels within the stomach of participants, measured at timepoints depending on the work package (WP). WP0 MRI on days 2, 7, 14, and 25.
3. Excretion of hydrogels and no signs of ulceration or abrasion to the stomach lining of participants measured using gastroscopy at +28 days from the last dose of Sirona
4. Participant compliance measured using participant feedback at only record of the dose being taken for WP0, done throughout the study
5. Nausea impact measured using participant feedback 3 days after every dose of Sirona

WP1 and WP2:
1. The total number of reported Serious Adverse Events (SAEs) measured using throughout the study. All AEs observed by the Investigator or reported by the participant, whether or not attributed to Sirona, will be recorded in the eCRF by the study team with a full description including the nature, date and time of onset, determination of non-serious versus serious, severity (grades 1-5), causality (unrelated possibly, probably or related), and outcome of the event. AE data will be made available to the Chief Investigator (or designee) and the safety reviewers. Serious Adverse Event (SAE): an SAE is any adverse intervention experience occurring at any dose that results in any of the following outcomes:
1.1. Death

1.2. A life-threatening event (at risk of death at the time of the event)
1.3. Requires inpatient hospitalization or prolongation of existing hospitalization
1.4. A persistent or significant disability/incapacity, or
1.5. A congenital anomaly/birth defect in the offspring of a subject.
Important medical events that may not result in death, be life-threatening, or require hospitalisation may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
A distinction should be drawn between serious and severe AEs. A severe AE is a major event of its type. A severe AE does not necessarily need to be considered serious. For example, nausea which persists for several hours may be considered severe nausea but would not be an SAE. On the other hand, a stroke that results in a limited degree of disability may be considered a mild stroke, but would be an SAE as meets the definition of serious (above).
2. Gastric transit time of Sirona, determined by MRI reflecting the retention of hydrogels within the stomach of participants, measured at WP1 days 10, 20, 38 and 48; WP2 days 15 and 28
3. Excretion of hydrogels and no signs of ulceration or abrasion to the stomach lining of participants measured using gastroscopy at +28 days after the final dose of Sirona
4. Participant compliance measured using participant feedback at dosing and participant drop out measured throughout the study
5. Dietary and energy intake measured using participant feedback at ecological momentary assessments weekly and intake24 measurements
6. Product tolerance and acceptability measured using participant feedback at end of each work package – Quotative QA
7. Nausea impact measured using participant feedback on the nausea impact scale (MSSS – Motion Sickness Severity Scale) for 3 days after each dose of Sirona

Secondary outcome measures
WP2:
1. Glucose and HbA1c levels measured using venous blood samples at 3 and 6 months
2. Waist circumference measured using tape measure at baseline, 3 and 6 months
3. Quality of life and overall experience of repeated dosing with Sirona measured using a quality of life score (EUROQOL 5D-3L questionnaire) and Three Factor Eating Questionnaire (TFEQ) at baseline, 3 and 6 months and a qualitative interview at 6 months
4. Metabolomics measured using venous blood samples and stool samples at baseline, 3 and 6 months
5. Micronutrients measured using stool sampling at baseline, 3 and 6 months
6. Appetite measured using ecological momentary assessments weekly throughout the study
7. Dietary intake obtained from intake24 measurements at baseline, 3 and 6 months

Overall study start date
01/01/2022

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Males or females aged 18 to 65 years
2. Healthy volunteers
3. BMI 30-40 kg/m²

4. Be able to understand, read and write English
5. Should not be vegan (foods used in appetite measurements will be suited to vegetarians and meat-eaters)
6. Must be able to swallow a Sirona dummy tablet prior to enrolment on the study. Failure to swallow tablets will result in exclusion from the trial
7. Must pass the psychological evaluation (undertaken by a bariatric psychologist)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
46

Key exclusion criteria
1. Any oral medication being taken
2. People with known human immunodeficiency virus (HIV)
Note: Adults with HIV not on oral anti-retroviral drugs may participate in this study if their BMI is between 30-40 kg/m²
3. Non-ambulatory
4. Hiatal hernia >3 cm
5. Positive for H. pylori
6. People with active gastric or duodenal ulcer disease
7. Previous gastric or oesophageal surgery
8. Severe oesophagitis
9. History of psychiatric disorders (OCD, depression, bulimia nervosa and anorexia nervosa)
10. Associated severe systemic disease not amenable to improvement with weight loss
11. People with inflammatory bowel diseases
12. People on anticoagulant treatment or steroids
13. Addiction to drugs or alcohol
14. People with gastric or oesophageal varices
15. Proton pump inhibitor (PPI) current usage
16. Pregnant or foreseeable pregnancy during the study or lactating females
17. People who smoke including cigarettes, pipes, cigars, hookahs and e-cigarettes
18. People who, in the opinion of the Investigator, may be non-compliant with study schedules or procedures
19. People with contraindications for MRI

Date of first enrolment
27/10/2022

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Southmead Hospital
Southmead Road
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Sponsor information

Organisation
Oxford Medical Products

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Sponsor type
Industry

Website

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Funder(s)

Funder type
Industry

Funder Name
Oxford Medical Products Limited

Results and Publications

Publication and dissemination plan
The study sponsor Oxford Medical Products (OMP) owns the data arising from the study. On completion of data analysis, a final report will be prepared and submitted to the ethics committee that approved the study. Any publications that arise from the study prepared by the chief investigator or co-investigators will first be approved by the sponsor prior to submission.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
Due to the commercial stage of the company and the competitive environment, the researchers will not be releasing the dataset for this study. They hope to in future studies.

The data management will be outsourced to Emmes to ensure rigorous GCP, data compliance and safe-guarding of the quality and integrity of the data.The system is 21CFR Part 11, EU GMP Annex 11, GDPR and HIPAA adherent. All data is backed up and an audit trail maintained.

Emmes will manage the electronic database (eCRF) - including maintenance of the SOPs for the use of the system.

System security will be in place to protect against unauthorised access, and only individuals with authorised will be able to use the system. Emmes will provide web-based access, query management and resolution, and customisable reports.

All iterations of data will be clearly identified ensuring that it is possible to compare the original data and observations with the processed data. An unambiguous participant identification code that allows identification of all the data reported for each participant will be used. TheSponsor' sTrial Master File (TMF) (paper) will be maintained by the CRO, with oversight from the Sponsor, and the CI/PI will maintain the Investigator Site File (ISF) at each site. Both files will be kept in secure locations with restricted access to authorised personnel.

Direct access will be granted to authorised representatives from the Sponsor, host institution and the REC to permit trial-related monitoring, audits and inspections, in line with participant consent. The study protocol, documentation, data and all other information generated will be

held in strict confidence. No information concerning the study or the data will be released to any unauthorised third party, without prior written approval of the sponsor.

The study monitor (CRO) will review all study data in line with the study monitoring plan to ensure the safety and wellbeing of participants, the integrity of study data and compliance with GCP.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	WP1 version 1.1	11/04/2022	05/05/2022	No	Yes
Participant information sheet	WP2 version 1.1	11/04/2022	05/05/2022	No	Yes
HRA research summary			26/07/2023	No	No
Participant information sheet	version 2.1	04/01/2024	23/02/2024	No	Yes
Abstract results	Abstract GC4.211; questionnaire results	08/05/2024	14/04/2025	No	No
Abstract results	Abstract GC4.212; results	08/05/2024	14/04/2025	No	No
Abstract results	Abstract GC4.213; Preliminary intention to treat analysis results	08/05/2024	14/04/2025	No	No
Abstract results	Poster-115; Baseline characteristics	19/11/2024	14/04/2025	No	No
Abstract results	Poster-538; Reduced Dietary Intake	19/11/2024	14/04/2025	No	No
Other publications	Poster-490; Hydrogel development	16/11/2023	14/04/2025	Yes	No
Abstract results	Abstract 107488; Effects on appetite	01/08/2024	16/04/2025	No	No