ISRCTN70821789 https://doi.org/10.1186/ISRCTN70821789

Trial to compare the efficacy and safety of GA-AT0719 versus simethicone in the treatment of excessive gas in the intestines (bloating)

Submission date	Recruitment status	[_] Prospectively registered
07/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/12/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2025	Digestive System	

Plain English summary of protocol

Current plain English summary as of 06/04/2022:
Background and study aims
Functional gastrointestinal disorders (FGIDs) are a group of bowel disorders which are dominated by a feeling of abdominal fullness or bloating. Bloating is usually absent on awakening and worsens throughout the day. It may be intermittent and persists over several days. Bloating could arise without any predisposing factors and is unlikely to be completely resolved with medication and lifestyle modification.
Bloating is a common symptom that is reported by 6% to 31% of the general population. It is usually considered the sensation that is associated with abdominal distension (i.e. the visible increase in abdominal girth).
Simethicone is an inert substance with an antifoaming activity that reduces bloating, abdominal discomfort, and abdominal pain by promoting the clearance of excess gas along the gastrointestinal tract (digestive system).
One of possible reasons for bloating and distension is abnormal levels of bacteria in the small intestine, resulting in too much gas in the intestine. An imbalance of microorganisms that usually live in the bowel can sometimes be the result of antibiotic treatment. GA-AT0719 may reduce the interaction of microorganisms with the bowel, preventing the increase in gas content.
The aim of this study is to assess the effectiveness and safety of GA-AT0719 compared with simethicone in adult patients with abdominal bloating and distension.

Who can participate?
Caucasian adults aged between 18 and 65 with functional abdominal bloating and distention

What does the study involve?
Participants are randomly allocated to take GA-AT0719 or simethicone by mouth for 20 consecutive days.

What are the possible benefits and risks of participating?
This treatment could be very useful for the treatment of abdominal bloating and distention by reducing the associated symptoms. No adverse reactions to the study product have been reported.

Where is the study run from?
Devintec Sagl (Switzerland)

When is the study starting and how long is it expected to run for?
December 2019 to June 2020

Who is funding the study?
Devintec Sagl (Switzerland)

Who is the main contact?
Alina Iordache
alina.iordache@cebis-int.com

Previous plain English summary:
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Functional gastrointestinal disorders (FGIDs) are a group of bowel disorders which are dominated by a feeling of abdominal fullness or bloating. Bloating is usually absent on awakening and worsens throughout the day. It may be intermittent and persists over several days. Bloating could arise without any predisposing factors and is unlikely to be completely resolved with medication and lifestyle modification.
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What does the study involve?
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Who is the main contact?
Alina Iordache
alina.iordache@cebis-int.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CEBNOV29072019

Study information

Scientific Title
A double-blind, multicentre, randomized, parallel-group trial to compare efficacy and safety of GA-AT0719 versus simethicone in the treatment of functional abdominal bloating and distention

Acronym
CONFORT ST

Study objectives
This randomized, double-blind clinical study evaluates the efficacy and safety of GA-AT0719 vs simethicone in adult patients with bloating and distension in functional gastrointestinal disorders (FGIDs).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 17/12/2019, National Committee of Bioethics of Medicines and Medical Devices (Stefan Cel Mare 19-21 Road, District 2, Bucharest, Romania; +40 (0)212102880; no email provided), ref: 2DM
2. Approved 27/12/2019, Ethics Committee for Clinical Trials (8 Damyan Gruev Str., Sofia 1303, Bulgaria; +359 (0)2 8903555; bda@bda.bg), ref: ЕКК*И*/СТ-1234/27-12-2019

Study design
Double-blind parallel randomized multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Functional abdominal bloating and distention

Interventions
Current intervention as of 06/04/2022:
Participants are randomized in a 1:1 ratio to GA-AT0719 or simethicone. Both products are administered three times per day by oral route for 20 days consecutively.

At the baseline visit (V1) participants perform the Hydrogen Breath Test (HBT) to confirm Small Intestinal Bacterial Overgrowth (SIBO). Glucose digestion is measured from hydrogen production using HBT measurements over 2 hours following glucose challenge. The Likert scale was used to measure the abdominal girth at every visit at the doctor’s office. The participants are re-evaluated using the Hydrogen Breath Test at day 20 (V4).

HBT is performed under fasting conditions and after ingesting 50 g of glucose dissolved in 250 ml of water. Over a 2-hour period, breath samples are collected at 30-min intervals (e.g., from 8 am until 10 am). A positive HBT is defined as a hydrogen gas elevation of 12 parts per million (ppm) at two timepoints within the 30 min in 2 hours following a glucose-loading dose (ideally for two consecutive measurements).

Participants' visits:
1. Baseline visit
2. Day 2 of treatment
3. Day 10 of treatment
4. Day 20 of treatment

Previous intervention:
Participants are randomized in a 1:1 ratio to GA-AT0719 or simethicone. Both products are administered three times per day by oral route for 20 days consecutively.

At the baseline visit (V1) participants perform the Hydrogen Breath Test (HBT) to confirm Small Intestinal Bacterial Overgrowth (SIBO). Glucose digestion is measured from hydrogen production using HBT measurements over 2 hours. FAB symptoms are measured by the subject's self-assessment of symptoms, bloating, distension, and abdominal pain by Likert scale following the glucose challenge test and measuring abdominal girth at every visit to the doctor's office. The participants are re-evaluated using the Hydrogen Breath Test at day 20 (V4).

HBT is performed under fasting conditions and after ingesting 50 g of glucose dissolved in 250 ml of water. Over a 2-hour period, breath samples are collected at 30-min intervals (e.g., from 8 am until 10 am). A positive HBT is defined as a hydrogen gas elevation of 12 parts per million (ppm) at two timepoints within the 30 min in 2 hours following a glucose-loading dose (ideally for two consecutive measurements). After completion of the 20-day treatment period, the participants will be followed-up for 10 days.

Participants attend five visits:
1. Baseline visit
2. Day 2 of treatment
3. Day 10 of treatment
4. Day 20 of treatment
5. Day 30, 10 days after visit 4

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
GA-AT0719, simethicone

Primary outcome measure
Current primary outcome measure as of 08/04/2022:
1. Occurrence of adverse events: frequency, intensity and relation with the administered treatments measured using case report forms during the study period
2. Clinical parameters monitored and vital signs examined between pre- and post-study visits:

2.1. Physical examination (height, weight, blood pressure, temperature, BMI) at Day 0 and Day 20
2.2. Safety assessed using patient's report at Day 0, Day 2, Day 10, and Day 20

Previous primary outcome measure as of 06/04/2022:
1. Occurrence of adverse events: frequency, intensity and relation with the administered treatments measured using case report forms during the study period
2. Clinical parameters monitored and vital signs examined between pre- and post-study visits:
2.1. Physical examination (height, weight, blood pressure, temperature, BMI) at Day 0 and Day 20
2.2. Safety assessed using patient's report at Day 0, Day 2, Day 10, Day 20 and Day 30

Previous primary outcome measure:
1. Occurrence of adverse events: frequency, intensity and relation with the administered treatments measured using case report forms during the study period
2. Clinical parameters monitored and vital signs examined between pre- and post-study visits:
2.1. Physical examination (height, weight, blood pressure, temperature, BMI) at Day 0, Day 20 and Day 30
2.2. Evaluation of stool based on Bristol scale at Day 0, Day 2, Day 10, Day 20 and Day 30
2.3. Safety assessed using patient's report at Day 0, Day 2, Day 10, Day 20 and Day 30

Secondary outcome measures
Current secondary outcome measures as of 06/04/2022:
1. Symptomatology of bloating and distention in FGIDs
2. Onset of effectiveness: time to onset of symptoms improvement assessed with visual analogue scale (VAS) before, at 60 and 120 min after the dose of the first 8 days of therapy
3. Symptomatology of bloating and distention in FGIDs, possibly caused by SIBO assessed using a Hydrogen Breath Test at Day 1 (V1) and Day 20 (V4)

Previous secondary outcome measures:
1. Symptomatology of bloating and distention in FGIDs assessed using the Likert gastrointestinal symptom score (GIS) scale using a daily journal kept for the entire period of the study treatment and throughout the 10-day follow-up period and by measuring abdominal girth at every visit to the doctor's office
2. Onset of effectiveness: time to onset of symptoms improvement assessed with visual analogue scale (VAS) before, at 60 and 120 min after the dose of the first 8 days of therapy
3. Symptomatology of bloating and distention in FGIDs assessed using a Hydrogen Breath Test at Day 1 (V1) and Day 20 (V4)

Overall study start date
17/12/2019

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Adults between 18 and 65 years of age
2. Caucasian race
3. Suffering from functional abdominal bloating and distention

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
88

Total final enrolment
88

Key exclusion criteria
1. Pregnant women or breastfeeding
2. Unwilling to sign the informed consent form
3. Allergy to one of the product ingredients
4. Unable to come to the study visits
5. Health status not allowing participation in the study
6. Diabetic patients
7. Patients diagnosed with celiac disease
8. Patients treated with antibiotics 2 weeks prior to the Hydrogen Breath Test schedule
9. Patients who were using purgatives within 2 weeks prior to the Hydrogen Breath Test

Date of first enrolment
16/01/2020

Date of final enrolment
20/05/2020

Locations

Countries of recruitment
Bulgaria

Romania

Study participating centre
Zlatka Etropolska
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Study participating centre
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BROD - Ambulatory Practice for Primary Medical Care EOOD
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Study participating centre
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Study participating centre
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ENDODIGEST Medical Centre
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410151

Sponsor information

Organisation
Devintec Sagl

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+41 91 601 40 51
info@devintecpharma.com

Sponsor type
Industry

Website
http://www.devintecpharma.com

Funder(s)

Funder type
Industry

Funder Name
Devintec Sagl

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents will be provided at a later point.

Intention to publish date
28/02/2021

Individual participant data (IPD) sharing plan
The data will be collected under the study confidentiality and for the study purpose only, according to the approved informed consent form. The study data will be archived according to the sponsor requirements and local regulatory requirements.

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			04/01/2021	No	Yes
Participant information sheet			04/01/2021	No	Yes
Results article		03/11/2023	13/02/2025	Yes	No