

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

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

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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What does the study involve?

Participants are randomly allocated to take GA-AT0719 or simethicone by mouth for 20 consecutive days. After completion of the 20-day treatment period, the participants will be followed-up for 10 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.

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

Contact information

Type(s)
Scientific

Contact name
Mrs Alina Iordache

ORCID ID
<https://orcid.org/0000-0002-5931-0463>

Contact details
222 Calea Plevnei 3rd Floor
Bucharest
Romania
060016
+40 737 640 721
alina.iordache@cebis-int.com

Additional identifiers

Protocol serial number
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: EKKN/CT-1234/27-12-2019

Primary study design

Interventional

Study design

Double-blind parallel randomized multicentre study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

Ambulatory Practice for Primary Outpatient Medical Care SANA OOD

8 Akademik Stefan Mladenov Street

Sofia

Bulgaria

1700

Study participating centre**Kiril Elenski**

BROD - Ambulatory Practice for Primary Medical Care EOOD

23 Petko D. Petkov Str

Plovdiv

Bulgaria

4000

Study participating centre**Emiliya Dimitrova**

Medical Centre Prolet EOOD

25 Olimpi Panov Str., fl. 2

Ruse
Bulgaria
7000

Study participating centre
Corina Petrisor
ENDODIGEST Medical Centre
5 Olimpiadei Street
Oradea
Romania
410151

Sponsor information

Organisation
Devintec Sagl

Funder(s)

Funder type
Industry

Funder Name
Devintec Sagl

Results and Publications

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

