

The effects of a non-alcoholic beer enriched in soluble fibre compared with a non-alcoholic beer without fibre on bowel function in healthy subjects

Submission date 07/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/04/2010	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Rosa Sola

Contact details

Hospital Universitari Sant Joan
Facultat de Medicina i Ciències de la Salut
C/ Sant Llorenç, nº 21
Reus
Spain
43201

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Pilot study of nutritional intervention randomised, parallel, double-blind, placebo-controlled trial to assess the effects of the administration of a non-alcoholic beer enriched in soluble fibre compared with a non-alcoholic beer without fibre on bowel function in healthy subjects

Acronym

Beer soluble fibre 01

Study objectives

The inclusion of a significant content of soluble fibre in non-alcoholic beer positively affects markers of intestinal motility and colonic transit time, contributing to the prevention of constipation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Comité Ètic d'Investigació Clínica Hospital Universitari Sant Joan, REUS (Spain) approved on the 29th October 2009 (ref: 09-10-29/10 assN1)

Study design

Randomised parallel double-blind placebo controlled pilot trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Bowel function

Interventions

Participants will take, during the 3 days prior to the simple abdominal Rx, 20 radio-opaque markers by day at the same time that the Rx will take place. If more than 10 radio-opaque markers are present in plaque, the participant will be entered into the study and will be

delivered the product allocated by randomisation. Non-alcoholic beer enriched or without soluble fibre (250 mL) should be taken half an hour before dinner during the 21 days. At the end of the intervention the simple abdominal Rx with radio-opaque markers was repeated, with the 3 days prior to observe the effects of non-alcoholic beer enriched in soluble fibre on intestinal transit.

Participants must maintain their usual diet, monitored by a 3-day food record at the beginning and end of intervention, their physical activity that will be controlled by a physical activity questionnaire at the beginning, in the middle and the end of intervention and their fluid intake that will be recorded at the beginning, in the middle and the end of intervention.

The control group consume non-alcoholic beer without soluble fibre. The total duration is 21 days for each arm (intervention group and control group).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Soluble fibre

Primary outcome measure

Colonic transit time, measured at inclusion (day 1) and at the end of the study (day 21)

Secondary outcome measures

Measured at inclusion (day 1) and at the end of the study (day 21):

1. Anthropometric measures
2. Control of the deposition rate and Bristol Scale Stool form
3. Satiety degree
4. General biochemical profile (lipid profile and insulin resistance)

Overall study start date

18/11/2009

Completion date

30/03/2010

Eligibility

Key inclusion criteria

1. Adults aged 18 to 65 years, either sex
2. Subject that consider normal bowel habits range using criteria of 1 stool per day to 1 stool every 3 days
3. Subject that after understand the protocol and the study process has provided written informed consent to participate in the study
4. Subject consider healthy according to medical history, physical examination and laboratory tests available
5. Subject after the study of colonic transit time in the simple abdominal X-ray (RX) note the

presence of some radio-opaque marker

6. In women of childbearing age must have a urine pregnancy test negative within 48 hours prior to each day of the radiographic study

7. Absence of abdominal surgery except appendectomy or herniorrhaphy

8. Failure to take medication or drugs that alter intestinal motility (natural products including laxatives, antidiarrhoeals and antispasmodics)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

32

Key exclusion criteria

1. Subject that required treatment with laxatives, fibre and/or bulking agents (not digestible) in the 2 weeks prior start the study

2. Subject after the study of colonic transit time in the simple abdominal X-ray (RX) NOT observe the presence of 10 or less radio-opaque marker

3. Subject during the week preceding the study received treatment for faecal impaction enema

4. Subjects who suffer from constipation secondary to other diseases (Hirschsprung disease, hypothyroidism, mental retardation, psychiatric disorders, neurological disorders, major abdominal or extraabdominal surgery)

5. Subjects with renal insufficiency, hypocalcaemia, hypercalcaemia, or any metabolic disorder at baseline (or is detected) during the study

6. Subjects with secondary gastrointestinal and systemic disorders

7. Subjects who have used drugs that may affect intestinal motility (natural products including laxatives, antidiarrhoeals and antispasmodics)

8. Inability to understand the study, its process and the needs required by the subject

9. The subject is participating in a clinical trial or received an investigational product within thirty days prior to selection/inclusion in the study

10. To have coeliac disease

11. Allergy to alcohol-free beer

12. Being pregnant or lactating

Date of first enrolment

18/11/2009

Date of final enrolment

30/03/2010

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Universitari Sant Joan

Reus

Spain

43201

Sponsor information

Organisation

Technology Centre of Nutrition and Health (Centre Tecnològic de Nutrició I Salut [CTNS]) (Spain)

Sponsor details

c/o Francesc Puiggros

Camí de Valls, 81-87

Reus

Spain

43204

Sponsor type

Research organisation

Website

<http://www.ctns.cat>

ROR

<https://ror.org/00mzj5z57>

Funder(s)

Funder type

Research organisation

Funder Name

Technology Centre of Nutrition and Health (Centre Tecnològic de Nutrició I Salut [CTNS]) (Spain)

Funder Name

HeSA (Spain)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration