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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	[_] Prospectively registered [_] Protocol
Registration date 15/04/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/04/2010	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 extraabodominal 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