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The effect of Milk Thistle extract versus tea on serum iron increase after a meal containing non-haem iron in Hereditary Haemochromatosis: a pilot study

Submission date
28/07/2006

Recruitment status
No longer recruiting

Registration date
12/09/2006

Overall study status
Completed

Last Edited
25/02/2013

Condition category
Nutritional, Metabolic, Endocrine

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

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

Acronym
MTHH

Study objectives
We hypothesise that consumption of milk thistle extract with a meal containing non-haem iron leads to a reduction in serum iron increase following the meal, due to the formation of iron-silybin complexes that render iron unavailable for mucosal uptake, but the milk-thistle-related reduction in post-prandial serum iron increase is not equal to the tea-related reduction in post-prandial serum iron increase.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by King's College Hospital REC on 21st April 2006 (reference number 06/Q0703/56).

Study design
Open-intervention pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Hereditary Haemochromatosis (HH)

Interventions

The treatment intervention will consist of Legalon 140 mg (Madaus GmbH, Germany) milk thistle extract on one occasion with test meal. The comparator intervention will be a tea beverage on one occasion with test meal. The control will be the test meal with water.

All patients will ingest the treatment (Milk Thistle capsule) with a meal, the comparator (tea) with an identical meal and control (the meal alone) on three separate occasions, four to seven days apart, and in a random order. The meal will contain 15.2 mg non-radioactive non-haem iron and will consist of vegetarian shepherd's pie, fruit salad and juice. On each occasion, blood will be drawn once before and once hourly for four hours after the meal, for measurement of total serum iron.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Legalon 140 mg (milk thistle extract)

Primary outcome measure
Serum iron increase after the test meal on each of three occasions (meal with milk thistle, versus meal with tea, versus meal with water).

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/08/2006

Completion date
16/10/2006

Eligibility

Key inclusion criteria
1. Patients will be homozygous for the C282Y mutation of the HFE gene (the genotype associated with type one hereditary haemochromatosis), and have phenotypic haemochromatosis (identified by raised serum iron levels on diagnosis), as this is the particular group of interest which may benefit from interventions to reduce dietary iron absorption
2. ALL patients will be fully treated (i.e. undergoing phlebotomy to maintain iron stores within the normal range, following on from the removal of primary iron burden at diagnosis), in order to reduce variability in the data as iron absorption varies between fully treated and untreated /newly diagnosed patients
3. Patients will be adults (aged 18 or over), as type one hereditary haemochromatosis presents in adulthood

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Patients with allergy to any foods or medicines will be excluded from participating for their own safety
2. Patients with gastrointestinal diseases which alter gut motility, gut permeability or gastric pH (ulcerative colitis, Crohn's disease, coeliac disease,
gastric ulceration) will also be excluded from participating as these disorders affect gastrointestinal function and, thus, may result in altered iron absorption and confound the results of the study

Date of first enrolment
16/08/2006

Date of final enrolment
16/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Nutrition and Dietetics
London
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
This project is funded by the Haemochromatosis Society (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2010		Yes	No