

# 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

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<b>Registration date</b> 12/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/02/2013	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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****Organisation**

King's College London (UK)

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**Sponsor type**

University/education

**Website**

<http://www.kcl.ac.uk>

**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?
<a href="#">Results article</a>	results	01/10/2010		Yes	No