

A study to evaluate the immune health benefits of two selected probiotic strains

Submission date 08/12/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/12/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/04/2012	Condition category Signs and Symptoms	☐ 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

Protocol serial number
HND-IM-001

Study information

Scientific Title
Randomised, double-blind, placebo-controlled trial to evaluate the impact of a minidrink or capsule containing selected probiotic strains on the immune response following an influenza vaccination in healthy adults

Acronym
IMPRESS

Study objectives

The study was designed to investigate the immune modulating properties of two probiotic strains in an influenza vaccination model.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of the Luigi Sacco Hospital in Milan, Italy, approved on the 19th February 2009 (ref: 72/09/101/08/AP)

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled parallel-group single-centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

General immune defence

Interventions

Four different treatment arms are included in the study:

1. A capsule containing *Bifidobacterium animalis* ssp. *lactis* (BB-12®) in a dosage of minimum 1 billion CFU (colony forming units)/day
2. A placebo capsule
3. A milk-based minidrink containing the probiotic strain *Lactobacillus paracasei* ssp. *paracasei* (L. casei 431®) in a dosage of minimum 1 billion CFU/day
4. A placebo minidrink

Study products to be taken orally once daily for six weeks. Ten weeks follow-up after end of supplementation phase.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Bifidobacterium animalis ssp. *lactis* (BB-12®), *Lactobacillus paracasei* ssp. *paracasei* (L. casei 431®)

Primary outcome(s)

Antigen-specific response to the influenza vaccination in plasma and saliva 4 weeks after the vaccination.

Key secondary outcome(s)

General adaptive and innate immune responses to the influenza vaccination 4 weeks after the vaccination.

Completion date

31/08/2009

Eligibility

Key inclusion criteria

1. Healthy male and female subjects
2. Aged 20 - 60 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Presence of acute or terminal disease
2. Gastrointestinal disorders or surgery
3. Intolerance for milk protein or lactose
4. Daily consumption of probiotic products
5. Antibiotic treatment
6. Any vaccination 15 days prior to baseline
7. Prior influenza vaccination for the 2008/2009 season
8. Already having suffered from influenza during the 2008/2009 season

Date of first enrolment

20/02/2009

Date of final enrolment

31/08/2009

Locations

Countries of recruitment

Denmark

Italy

Study participating centre

Boege Allé 10-12
Hoersholm
Denmark
2970

Sponsor information

Organisation

Chr. Hansen A/S (Denmark)

ROR

<https://ror.org/01mv6bt66>

Funder(s)

Funder type

Industry

Funder Name

Chr. Hansen A/S (Denmark)

Results and Publications

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	01/03/2012		Yes	No