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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/12/2010	**Overall study status** Completed	
Last Edited 18/04/2012	**Condition category** Signs and Symptoms	

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
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)

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

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

Overall study start date
20/02/2009

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

Age group
Adult

Sex
Both

Target number of participants
220 subjects, 55 in each arm

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)

Sponsor details
Boege Allé 10-12
Hoersholm
Denmark
2970

Sponsor type
Industry

Website
http://www.chr-hansen.com/

ROR
https://ror.org/01mv6bt66

Funder(s)

Funder type
Industry

Funder Name
Chr. Hansen A/S (Denmark)

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	01/03/2012		Yes	No