Effect of Chitosan on Health and Obesity

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|---------------------------------|--|--|--|--|
| 16/12/2002 | | ☐ Protocol | | |
| Registration date 16/12/2002 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 08/11/2022 | Nutritional, Metabolic, Endocrine | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Cliona Ni Mhurchu

Contact details

Clinical Trials Research Unit University of Auckland Private Bag 92019 Auckland New Zealand

+64 (0)9 373 7599 ext 84494 c.nimhurchu@ctru.auckland.ac.nz

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

HRC 01/416

Study information

Scientific Title

Effect of Chitosan on Health and Obesity

Acronym

ECHO

Study objectives

Results from trials of chitosan as a weight loss treatment have provided conflicting results. A 1998 review of 5 studies suggested that chitosan was an effective treatment for overweight and obesity. However, many more chitosan trials have been carried out since then with variable results. In order resolve the uncertainty surrounding the effectiveness of this dietary supplement, we conducted a large randomised controlled clinical trial of the effect of chitosan on body weight, lipids, and other health outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Obesity

Interventions

3 g Chitosan daily versus placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Chitosan

Primary outcome(s)

The primary aim of the ECHO study was to determine if chitosan was an effective weight loss treatment for people who were overweight or obese.

Measures included changes in body weight (kilograms); body mass index, waist circumference; body fat percentage; systolic and diastolic blood pressure; serum cholesterol and lipids; plasma

glucose; fat-soluble vitamins; faecal fat losses and health-related quality of life, from baseline to 24 weeks.

Key secondary outcome(s))

Not provided at time of registration

Completion date

30/06/2003

Eligibility

Key inclusion criteria

- 1. Overweight/obese male or female volunteers
- 2. Aged greater than 18 years
- 3. Body Mass Index (BMI) between 28 50 kg/m^2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2001

Date of final enrolment

30/06/2003

Locations

Countries of recruitment

New Zealand

Study participating centre Clinical Trials Research Unit

Auckland New Zealand

Sponsor information

Organisation

Health Research Council of New Zealand (New Zealand)

ROR

https://ror.org/00zbf3d93

Funder(s)

Funder type

Research council

Funder Name

The Health Research Council of New Zealand (New Zealand)

Funder Name

Healtheries of New Zealand Ltd (New Zealand)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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 | | 01/09/2004 | | Yes | No |
| Results article | | 17/12/2004 | | Yes | No |
| Other publications | Systematic review | 01/02/2005 | | Yes | No |