

Effects of pectin liquid on gastroesophageal reflux disease in children with cerebral palsy

Submission date 24/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/04/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Reiko Miyazawa

Contact details
Department of Pediatrics and Developmental Medicine
Gunma University Graduate School
3-39-22
Showa-machi
Maebashi
Gunma
Japan
371-8511
+81 27 220 8205
rmiazaw@med.gunma-u.ac.jp

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Changing feeding style is an alternative therapy for decreasing GastroEsophageal Reflux (GER) - related symptoms. Use of thickeners is common and effective in decreasing frequent episodes of regurgitation or vomiting in infants, and in improving dysphagia in handicapped patients. We hypothesized that thickener is effective for GastroEsophageal Reflux Disease (GERD) in neurologically impaired children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was approved by the Human Investigation Committee of Gunma University on 17 February 2005. Informed consent was obtained from the mother of each subject.

Study design

Randomized single-blind controlled cross-over multicentre (2 hospitals) study.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Gastroesophageal Reflux Disease

Interventions

We enrolled 18 patients (16 male and 2 female) with cerebral palsy from 2 hospitals, Gunma University Hospital and Gunma Rehabilitation Centre for the Physically Handicapped Children. The average age of subjects was 11.7 ± 4.4 years old.

All patients received the enteral formula described below through a naso-gastric tube.

Phase 1: pH monitoring

The subjects were randomly allocated to the following 2 groups:

Group A (9 participants): Participants were fed with a high-pectin content diet (enteral formula: pectin liquid = 2:1 [v/v], intervention) and an enteral formula mixed with water added to a similar volume as the pectin liquid (non-pectin diet, control) in a cross-over manner.

Group B (9 participants): Participants were fed with a low-pectin content diet (enteral formula: pectin liquid = 3:1 [v/v], intervention) and a non-pectin diet (control) in a cross-over manner.

Esophageal pH of each participant was monitored over 48 hours while he/she was being fed with the formula described above.

Phase 2: Effects of pectin liquid on GERD symptoms

Group A: Nine patients were fed with a high-pectin content diet for 4 weeks (intervention), and with non-pectin diet (control) for 4 weeks in a cross-over manner.

Group B: Nine patients were fed with a low-pectin content diet for 4 weeks (intervention), and with non-pectin diet (control) for 4 weeks in a cross-over manner.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pectin

Primary outcome measure

The following were assessed by the esophageal pH monitoring:

1. The median values for the % time pH <4 at the lower and upper esophagus
2. Number of refluxes per day
3. Duration of longest reflux
4. Number of refluxes longer than 5 min

Secondary outcome measures

The following were assessed using the patient's chart filled by the nurse/clinician daily:

1. Number of episodes of vomiting per day
2. Number of gastric residue with bleeding
3. Volume of gastric residue
4. Cough score (cough and wheezing)
5. Frequency of oxygen use for dyspnea
6. Total volume of feeding per day
7. Time to return to school

Overall study start date

01/03/2005

Completion date

30/09/2007

Eligibility

Key inclusion criteria

1. Cerebral palsy
2. Age between 2 to 18

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

18

Key exclusion criteria

Patients who received a surgical operation for GERD.

Date of first enrolment

01/03/2005

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

Japan

Study participating centre

Department of Pediatrics and Developmental Medicine

Gunma

Japan

371-8511

Sponsor information

Organisation

Gunma University, Department of Pediatrics and Developmental Medicine (Japan)

Sponsor details

3-39-22

Showa-machi

Maebashi

Gunma

Japan

371-8511

Sponsor type

University/education

ROR

<https://ror.org/046fm7598>

Funder(s)

Funder type

University/education

Funder Name

The Gunma University Graduate School (Japan)

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	16/04/2008		Yes	No