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

Submission date	Recruitment status	[_] Prospectively registered
24/10/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/10/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/04/2008	Digestive System	

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

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
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Sponsor information

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

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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