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Bethanechol Chloride for prevention of bladder dysfunction after radical hysterectomy in gynecologic cancer patients: A Randomised controlled trial study

Submission date
14/07/2010

Recruitment status
No longer recruiting

Registration date
29/07/2010

Overall study status
Completed

Last Edited
05/10/2011

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Bethanechol Chloride for prevention of bladder dysfunction after radical hysterectomy

Study information

Scientific Title

Study objectives
To evaluate the efficacy of bethanechol chloride compared with placebo for prevention of bladder dysfunction in gynecologic cancer patients undergoing type III radical hysterectomy

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of the Faculty of Medicine, Chulalongkorn University approved on the 19th of July 2007 (ref: 484/2007)

Study design
Randomised placebo controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Bladder dysfunction after radical hysterectomy

Interventions
Treatment group received bethanechol chloride (Ucholine®) 20 mg three times a day, 1 hour before meal on 3rd -7th postoperative day (POD).
The control group received a placebo which had a similar appearance to bethanechol chloride.
Participants will have regular visits every 3 months within the first 2 years, then 4-6 months until 5 years.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Bethanechol chloride (Ucholine®)

Primary outcome(s)
The incidence of urethral catheter removal at 1 week postoperatively

Key secondary outcome(s))
1. Median duration of urethral catheterization
2. Adverse events
3. Incidence of urinary tract infection at 1 month postoperatively

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. Early stage cervical cancer or endometrial cancer patients who have undergone type III radical hysterectomy
2. Age 20-75 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Hypersensitivity to bethanechol chloride
2. Active bronchial asthma
3. Hyperthyroidism
4. Hypotension
5. Tachycardia
6. Vasomotor instability
7. Coronary artery disease
8. Epilepsy
9. Parkinsonism
10. Gastrointestinal obstruction
11. Bladder neck obstruction
12. Recent urinary bladder surgery
13. Gastrointestinal resection with anastomosis

Date of first enrolment
01/08/2007

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
Thailand

Study participating centre
Department of Obstetrics and Gynecology
Bangkok
Thailand
10330

Sponsor information

Organisation
Chulalongkorn University (Thailand)

ROR
https://ror.org/028wp3y58

Funder(s)

Funder type
University/education

Funder Name
Chulalongkorn University (Thailand) - Faculty of Medicine, Ratchadapiseksompotch Fund (Grant No.: RA049/50)

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	01/05/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes