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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
The incidence of urethral catheter removal at 1 week postoperatively

Secondary outcome measures
1. Median duration of urethral catheterization
2. Adverse events
3. Incidence of urinary tract infection at 1 month postoperatively

Overall study start date
01/08/2007

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

Age group
Adult

Sex
Both

Target number of participants
62

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)

Sponsor details
Ratchadapiseksompotch Fund
Faculty of Medicine
1873 Rama IV
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Sponsor type
University/education

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

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	01/05/2011		Yes	No