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The PROOF trial: PROtecting Ovaries and Fertility during chemotherapy

Submission date	Recruitment status	[ ] Prospectively registered
15/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/01/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/02/2019	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sonya Kashyap

Contact details
Clinical Epidemiology Program
Ottawa Hospital Research Institute (OHRI) (Canada) - formerly Ottawa Health Research Institute
Ottawa Hospital
Civic Campus, Room C405
1053 Carling Ave.
Ottawa, Ontario
Canada
K1Y 4E9
+1 613 798 5555 ext. 19590
sokashyap@ohri.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00380406

Secondary identifying numbers
MCT-82329

Study information

Scientific Title
A randomised controlled trial of gonadotropin releasing hormone agonist (gnRHa) for fertility preservation in oncology patients

Acronym
PROOF

Study objectives
Gonadotropin releasing hormone agonists will protect against ovarian failure and preserve measures of ovarian reserve in reproductive aged women undergoing gonadotoxic chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Research Ethics Board of the Ottawa Hospital (Canada) on the 10th May 2007 (for English-speaking patients) and 31st May 2007 (for French-speaking patients) (ref: 2006603-01H).

Study design
Multicentre, two arm, placebo based randomised parallel trial, with study participant, study investigator, caregiver, outcome assessor, and data analyst blinded.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Fertility preservation in female oncology patients

Interventions
Intervention group:
Lupron Depot (gonadotropin releasing hormone agonist - leuprolide acetate), trimonthly (every 3 months) intramuscular injections of 11.25 mg for 6 months with a maximum of 2 injections.

Control group:
Matching placebo without GnRHa, trimonthly (every 3 months) administration with a maximum of 2 injections.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lupron Depot (gonadotropin releasing hormone agonist - leuprolide acetate)

Primary outcome measure
Protection against ovarian failure measured at 12 months post cessation of chemotherapy.

Secondary outcome measures
Sonographic (biophysical) and biochemical markers of ovarian reserve:
1. Sonographic: pelvic ultrasound for ovarian volume and antral follicle count
2. Biochemical markers: FSH, oestradiol (E2), progesterone, luteinising hormone (LH), Inhibin A & B

The hormonal and ultrasound assessments will be done at 0, 3, 6, 9 and 12 months, in both study arms, post cessation.

Overall study start date
01/01/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Women who are:
1. Between ages 18 to 38
2. Who will be undergoing gonadotoxic (sterilising) curative/adjuvant chemotherapy for early stage disease; and
3. Have provided informed consent

All subjects will be enrolled from the Ottawa Hospital Regional Cancer Institute (OHRCC) and the Cancer Center of South Eastern Ontario at Kingston General Hospital (CCSEO).

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Female

Target number of participants
30

Key exclusion criteria
Women who:
1. Have advanced stage disease and/or whose median survival is expected to be less than 6 months
2. Have cancer of the ovaries, uterus, or fallopian tubes
3. Have clinical or biochemical evidence of diminished ovarian reserve (recent shortening of cycles less than 24 days between menses, age greater than 38, elevated serum follicular stimulating hormone (FSH) greater than 15 IU/L, or low antral follicle count (AFC - number of follicles less than 10 mm on day 2 or 3 of natural menses) on baseline pelvic ultrasound (less than 5) or elevated day 2 or 3 estradiol (greater than 280 pmol/ml)
4. Have previously received chemotherapy or abdominal/pelvic radiation or have planned to receive abdomino/pelvic radiation
5. Are pregnant
6. Have contraindications to intramuscular injections; or
7. Have a history of fractures secondary to/or documented osteoporosis

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Canada

Study participating centre
Clinical Epidemiology Program
Ottawa, Ontario
Canada
K1Y 4E9

Sponsor information

Organisation
Ottawa Hospital Research Institute (OHRI) (Canada) - formerly Ottawa Health Research Institute

Sponsor details
c/o Carolyn Adams-Smith, Director
Finance & Grants Admin
725 Parkdale Avenue
Ottawa, Ontario
Canada
K1Y 4E9
+1 613 798 5555 ext.13148
cadamssmith@ohri.ca

Sponsor type
Research organisation

Website
http://www.ohri.ca/

ROR
https://ror.org/03c62dg59

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-82329)

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