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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

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## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00380406

**Protocol serial number**
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).

### Primary study design
Interventional

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

### Study type(s)
Treatment

### 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(s)
Protection against ovarian failure measured at 12 months post cessation of chemotherapy.

### Key secondary outcome(s)
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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### 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
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## Sponsor information

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

### ROR
https://ror.org/03c62dg59

## Funder(s)

### Funder type
Research organisation

### Funder Name

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration