

The PROOF trial: PROtecting Ovaries and Fertility during chemotherapy

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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).

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

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

Canada

K1Y 4E9

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