ISRCTN28988709 https://doi.org/10.1186/ISRCTN28988709

Effects of chemotherapy upon female fertility

Submission date	Recruitment status	[ ] Prospectively registered
08/09/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/12/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/09/2015	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chemotherapy is a type of cancer treatment that can also lead to fertility problems in women of reproductive age. The effects of different types of chemotherapy on fertility are still unknown, and depend on the type of chemotherapy, dosage, duration and the patient's age. Recent studies have found that anti-mullerian hormone (AMH) is a valuable marker of fertility. The aim of this study is to find out about the risks to fertility of chemotherapy drugs and the accuracy of AMH in predicting women's fertility following chemotherapy.

Who can participate?
Women aged 18 - 43 who have been newly diagnosed with cancer (e.g., breast cancer or lymphoma).

What does the study involve?
Blood tests are used to assess AMH levels in cancer patients before chemotherapy and at follow up 6, 9 months and 1 year later, compared with healthy volunteers without known fertility problems of the same age. We hope to follow up patients for at least 5 years to assess their fertility following chemotherapy. A medical questionnaire is completed by all participants, giving their views on the information they received during the study.

What are the possible benefits and risks of participating?
Participants may not directly benefit from taking part in the study, but the results could help with decision-making regarding fertility treatment in the future. Risks of participation include the risks of blood tests.

Where is the study run from?
Warwick University (UK).

When is the study starting and how long is it expected to run for?
May 2010 to November 2011.

Who is funding the study?
Midland Fertility Services Ltd (UK).

Who is the main contact?
Dr Karolina Palinska-Rudzka
K.E.Palinska-Rudzka@warwick.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Karolina Palinska-Rudzka

Contact details
Centre House
Court Parade Aldridge
Walsall
United Kingdom
WS9 8LT
-
K.E.Palinska-Rudzka@warwick.ac.uk

Additional identifiers

Protocol serial number
8445

Study information

Scientific Title
Effects of chemotherapy upon fertility amongst women of reproductive age, using anti-mullerian hormone (AMH) as a marker of ovarian reserve

Study objectives
Accurate assessment of reproductive function in women following cancer treatment is increasingly important due to improvements in survival rates and development of new methods of fertility preservation.

Advance counselling regarding chemotherapy's potential to affect future plans for children, premature menopause and offering options for fertility preservation should be a vital, integrated part of care for young women.

Chemotherapy may lead to subfertility and loss of sex hormone production. The effects of different types of chemotherapy on ovarian reserve amongst women of reproductive age are still unknown. Chemotherapy-induced follicle loss is also dependent on the type of chemotherapy, its dosage, duration and age of patient.

Recent studies show that anti-mullerian hormone (AMH) is a valuable marker of ovarian reserve. It is independent of the menstrual cycle and can be accurate and diagnostic even amongst women without regular cycles.

We propose a prospective study to evaluate the risks to fertility of chemotherapeutic regimes and the accuracy of AMH in predicting women's potential reproductive capacity following chemotherapy. The results would be crucial in informing decision-makers and stakeholders regarding fertility treatment prognosis.

Using a prospective cohort design allows us to assess the effect of chemotherapy agents. Although the assays and analysis of AMH will be performed over a shorter period, we hope to followup patients for at least 5 years to begin to assess their post-chemotherapy fertility.
We will recruit 50 to 100 reproductive age women newly diagnosed with cancers, needing chemotherapy within the Cancer Network in West Midlands.

Serum AMH will be measured in patients before commencing chemotherapy and with follow up at 6, 9 months and 1 year compared with an age-matched control group without known fertility problems. 5 year follow-up will be performed.The sponsor of the study is Warwick University, a funder is MFS.

On 30/09/2015 the overall trial end date was changed from 26/11/2011 to 01/12/2016.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry and Warwickshire REC, November 2009, ref: 09/H1211/87

Study design
Multicentre observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network, Reproductive Health; Subtopic: All Cancers/Misc Sites; Disease: Miscellaneous

Interventions
1. Medical questionnaire, including questions regarding menstrual cycles, past medical history, desire to have children etc.
2. Venepuncture: serum AMH will be measured in patients before commencing chemotherapy and with follow up at 6, 9 months and 1 year compared with an age-matched control group

Study entry: other; patients are recruited at oncology/haematology clinics, or by contacting Midland Fertility Services.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
To assess the impact of different types, doses and duration of chemotherapy on ovarian reserve using AMH, measured at 6, 9, 12 and 60 months

Key secondary outcome(s))
To assess the accuracy of serum AMH testing in predicting future reproductive capacity, measured at 60 months

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Women aged 18 - 43 years
2. Newly diagnosed cancer - mainly with breast cancer and lymphoma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. A history of previous exposure to gonadotoxic agents and/or radiotherapy
2. Diagnosed with end stage cancer having a very poor prognosis (less than 10% chances of 1 year survival)
3. Significant ovarian pathology or previous bilateral oophrectomy

Date of first enrolment
26/05/2010

Date of final enrolment
26/11/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre House
Walsall
United Kingdom
WS9 8LT

Sponsor information

Organisation
University of Warwick (UK)

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Research organisation

Funder Name
Midland Fertility Services Ltd (UK)

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?
HRA research summary			28/06/2023	No	No