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Short versus long chemotherapy regiment for trophoblastic tumor

Submission date
19/02/2018

Recruitment status
No longer recruiting

Registration date
24/04/2018

Overall study status
Completed

Last Edited
15/03/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gestational trophoblastic neoplasm (GTN) is a type of neoplastic (tumor-like) condition after normal or abnormal pregnancy. This condition is usually resolved with initial diagnostic as well as therapeutic minor surgical procedure. After diagnosis of this condition, a few of them demonstrate persistent abnormality. This condition is treated with chemotherapy and is curable most of the time. There are different regimens to treat with chemotherapy and the most common ones require 5-8 days to complete a single cycle of treatment. This trial uses a less frequent dosing regimen that is completed in 2-3 days. The control treatment involves conventional regimen of alternate day injections for a week every 2 weeks and another experimental regimen involves two drugs each given only once every 2 weeks in a higher dose. Both of these drugs are approved but in different doses and dosing intervals. A less frequent dosing interval can increase patient compliance due to reduced duration of hospital admissions, less cost and operational feasibility in the hospital if the hypothesis is proven. This trial involves research and the purpose is to treat the GTN with two different regimens.
Participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled. Treatment regimen will be assigned randomly to assure equal chance of getting either treatment regimen.
Only low risk choriocarcinoma or persistent mole will be taken for the trial and participant should use effective contraception during the trial period. Trial period will extend up to 4 months. There will be blood work in the beginning and every two weeks thereafter. Chest X-ray and abdominal sonography will be done in the beginning.

Who can participate?
Women aged 18 years or over with post-molar GTN or choriocarcinoma, who have no other cancers and who are not breast-feeding.

What does the study involve?
Patients will be randomized to receive one of two combinations of chemotherapy drugs.

What are the possible benefits and risks of participating?
Participants in study arm might benefit from a shorter hospital stay compared with those in the

control arm. All trial drugs have the potential for side effects. Compensation and/or treatment is available to the subject in the event of trial-related injury. There is no extra incentive of any kind besides treatment required by the research. Treatment protocol will be as an intention to treat and lab tests and chemotherapeutic agents will be used as per usual practice. Thus there is no added cost to the patient.

Where is the study run from?
Paropakar Maternity and Women's Hospital, Kathmandu and other collaborating hospitals in Nepal

When is the study starting and how long is it expected to run for?
The study started in January 2018 and is expected to run for approximately 2 years.

How long will the trial be recruiting participants for?
The trial will be recruiting for approximately 11 months.

Who is the main contact?
Dr Gehanath Baral (gehanath@gmail.com)

Contact information

Type(s)
Scientific

Contact name
Dr Gehanath Baral

Contact details
Paropakar Maternity and Women's Hospital
Thapathali
Kathmandu
Nepal
GPO 8975 EPC 1553

Additional identifiers

Protocol serial number
1

Study information

Scientific Title
A phase III randomized trial of multi-day methotrexate versus biweekly pulse of methotrexate and actinomycin for the treatment of low-risk gestational trophoblastic neoplasia.

Study objectives
Less frequent combination treatment is not inferior to the multi-day single drug treatment in patients with low-risk gestational trophoblastic disease with respect to complete response.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Institutional Review Board, National Academy of Medical Sciences (IRB-NAMS), 27/06/2017, RG18-2017

Study design
phase III non-inferiority randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gestational trophoblastic neoplasia (GTN)

Interventions
Block randomization was done online at the site: https://www.sealedenvelope.com/simple-randomiser/v1/lists.
Experimental arm: Patients receive methotrexate 200 mg/m2 IV in 500 ml NS over 12 hours plus actinomycin 1 mg IV followed 24 hours later by folinic acid 15 mg PO/IV/IM BD for 2 days; cycle repeats every 2 weeks.
Active comparator arm: Patients receive methotrexate 50mg/m2 IM on days 1, 3, 5, and 7 and folinic acid 5 mg IV on days 2, 4, 6, and 8; cycle repeats every 2 weeks.
Follow-up will be at each 2-weekly cycle of chemotherapy, with 3-4 months required to complete the treatment cycle. Patients will be followed up for at least 1 year as per clinical protocol followed by the hospital.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Active comparator arm: Methotrexate and folinic acid Experimental arm: Methotrexate, folinic acid and actinomycin

Primary outcome(s)
Time to achieve serum β-hCG <5 mU/ml measured using the blood test at clinical laboratory of study site as a routine practice in the hospital prior to recruitment and then every 2 weeks before commencing each subsequent chemotherapy cycle until the level comes down to normal for two timepoints.

Key secondary outcome(s))
1. Total hospital admission days is measured using source document from treatment and discharge date.
2. Compliance to complete therapy is measured using defined follow up dates and rate of defaulter.

3. Need of high-risk regimen is measured by switch over into high-risk treatment regimen (if any).
4. Need of surgical intervention is measured using type of treatment received in each visit cycle.

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Histologically proven post molar GTN (Persistent mole for ≥4 months) or choriocarcinoma
2. Female
3. Age 18 years or above
4. WHO risk score of 6 or less
5. Willing to practice effective contraception for the duration of the study
6. Consented for participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Lactating
2. PSTT, non-gestational neoplasia
3. Abnormal CBC, LFT,RFT
4. Cancers in other organs

Date of first enrolment
29/01/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Nepal

Study participating centre
Paropakar Maternity and Women's Hospital
Thapathali
Kathmandu
Nepal
GPO 8975 EPC 1553, Kathmandu, Nepal

Sponsor information

Organisation
National Academy of Medical Sciences

ROR
https://ror.org/03pskkc12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date