

Short versus long chemotherapy regiment for trophoblastic tumor

Submission date 19/02/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/04/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/03/2018	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/01/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Maximum of 120

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

Sponsor details

Kanti Path

Kathmandu

Nepal

GPO:13606

Sponsor type

University/education

ROR

<https://ror.org/03pskkc12>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

It will be disseminated at the trial site and published in a peer reviewed journal. Presentation in professional society meetings/conferences.

Intention to publish date

31/12/2019

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