# Oral artesunate in metastasized cervix carcinoma

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
23/06/2010	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
21/07/2010	Completed	Results
Last Edited	Condition category	[] Individual participant data
21/07/2010	Cancer	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Alice Musibi

#### Contact details

Centre for Clinical Research (KEMRI) 5th Avenue Suites-Ngong Road 6th Floor P.O. Box 19829 Nairobi Kenya 00202

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

KEMRI SSC 1787

# Study information

#### Scientific Title

An open-label single centre dose-escalating phase I trial of oral artesunate in patients with metastasized cervix carcinoma

#### **Study objectives**

To determine the maximum tolerated dose (MTD) and the efficacy of orally administered artesunate in patients with metastasized cervical carcinoma.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Kenya Medical Research Institute (KEMRI) National Ethics Review Committee approved on the 11th May 2010 (ref. KEMRI SSC 1787)

#### Study design

Open-label single centre non-randomised dose-escalating phase I trial

#### Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

# Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

# Health condition(s) or problem(s) studied

Metastasized cervix carcinoma

#### **Interventions**

Patients will be recruited in cohorts of three and the starting dose will be 100 mg. Based on dose limiting toxicity evaluations, decisions regarding dose escalation or de-escalation on the next cohort will be made. Every cohort corresponds to a dose escalation of 50 mg. Daily oral artesunate will be administrated for a period of 28 days.

## Intervention Type

Drug

#### Phase

Phase I

### Drug/device/biological/vaccine name(s)

Artesunate

#### Primary outcome measure

Determination of maximum tolerated dose (defined as one dose level below that at which dose limiting toxicity [DLT] is observed in two or more of the patients), assessed during the treatment period of 28 days.

#### Secondary outcome measures

Objective tumour response and correlation to expression of markers in tumor biopsy samples, assessed after the treatment period of 28 days.

#### Overall study start date

01/07/2010

#### Completion date

01/03/2011

# **Eligibility**

#### Key inclusion criteria

- 1. Females aged 18 years or above
- 2. Diagnosed with cervix carcinoma stages IIIb, IVa and IVb
- 3. Overall good general condition (Eastern Cooperative Oncology Group [ECOG] performance status less than or equal to 2)
- 4. Written informed consent

## Participant type(s)

Patient

## Age group

Adult

# Lower age limit

18 Years

#### Sex

Female

# Target number of participants

15

#### Key exclusion criteria

- 1. Contraindication to use of artesunate due to hypersensitivity
- 2. Pregnant at time of recruitment
- 3. Human immunodeficiency virus (HIV) positive
- 4. History of hearing or balance problems
- 5. Weight of less than 50 kg or greater than 100 kg
- 6. On concomitant medication known to interact with artesunate
- 7. The following laboratory values obtained within 14 days prior to recruitment:

- 7.1. Absolute neutrophil count (ANC) less than 1,000 cells/mm3
- 7.2. Haemoglobin lower than 9.0 g/dL
- 7.3. Platelet count less than 100,000/mm3
- 7.4. Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase [SGOT]), alanine aminotransferase (ALT) (serum glutamic pyruvic transaminase [SGPT]), and alkaline phosphatase higher than 5 x upper limit of normal (ULN)
- 7.5. Total bilirubin higher than 1.5 x ULN

#### Date of first enrolment

01/07/2010

#### Date of final enrolment

01/03/2011

# Locations

#### Countries of recruitment

Kenya

# Study participating centre

Centre for Clinical Research (KEMRI)

Nairobi Kenya

00202

# Sponsor information

#### Organisation

Dafra Pharma Research and Development (Belgium)

# Sponsor details

Slachthuisstraat 30 bus 7 Turnhout Belgium 2300

#### Sponsor type

Industry

#### Website

http://www.dafra.be/start.html

# Funder(s)

# Funder type

Industry

#### Funder Name

Collaborative Programme Between:

#### Funder Name

Dafra Pharma Research and Development (Belgium)

#### Funder Name

Kenya Medical Research Institute (KEMRI) (Kenya)

# **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration