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Oral artesunate in metastasized cervix carcinoma

Submission date	Recruitment status	[ ] Prospectively registered
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	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
Objective tumour response and correlation to expression of markers in tumor biopsy samples, assessed after the treatment period of 28 days.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration