Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	AMC 102
Scientific Title	A Randomized Phase II Trial of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Paclitaxel and Carboplatin in HIV-Positive Women with Locally Advanced Cervical Cancer (LACC) (Version 3.0 09JUL2019)

Primary Sponsor Details

Sponsors *	University of California, Los Angeles (ICLA) (USA)

Secondary Sponsor Details

Contact for Public Queries

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Countries of Recruitment *

Zimbabwe

South Africa

Source of Funds	National Cancer institute (USA)
Health Condition(s) or Problem(s) Studied *	Women who are HIV-positive with incident locally-advanced cancer of the cervix (LACC).
Medicine Name *	I. CISPLATIN INJECTION II. PACLITAXEL INJECTION-USP 6mg/Ml III. CARBOPLATIN INJECTION BP 10mg/Ml IV. RADIATION THERAPY

Quantity of medicine required *	Cisplatin 10mg 2880 vials for 60 participants, Carboplatin 500mg 120 vials for 30 participants, Paclitaxel 300mg 120 vials for 30 participants

7.0 PRINCIPAL INCLUSION CRITERIA *

Inclusion Criteria

- Participants with locally advanced primary, untreated, histologically-confirmed, documented invasive squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma of the uterine cervix.
- HIV-1 infection
- All patients must be prescribed combination antiretroviral therapy
- Ability to understand and the willingness to provide informed consent to participate.
- Karnofsky performance status of > 60%.
- A negative urine or serum pregnancy test within 3 weeks prior to enrollment and agree to use an effective form of contraception (e.g., barrier contraception, highly effective hormonal contraception).
- Participants should be suitable for treatment with radical intent using concurrent chemotherapy and pelvic radiation.
- Life expectancy of greater than 6 months.

7.1 PRINCIPAL EXCLUSION CRITERIA *

- Participants who do not fulfill the above criteria
- Participants who have undergone hysterectomy.
- Acute active (such as tuberculosis or malaria), serious, uncontrolled infection.

7.2 PRIMARY END POINTS *

The primary endpoint, two-year progression-free survival (PFS), will be defined as the length of time from registration enrollment to disease recurrence, disease progression, or death for any reason. Participants who are alive and who did not experience disease recurrence or progression by the end of the study will be censored for PFS at the date of their last contact. The intervention arm will be compared to the control arm for improvement in PFS via one-sided log-rank test. This test will be conducted once for the interim analysis and once for the final analysis. The primary analysis on the primary efficacy endpoint will use the intention-totreat population. Additionally, the analysis on the primary efficacy endpoint will be performed using the per protocol population

9.0 DESIGN OF THE TRIAL

Type of trial *	Opened

If controlled

Randomised	Yes
Single Blind	No
Double Blind	No
Parallel group	No
Cross over	No
Other	Yes
If yes to other, specify	All participants will receive Cisplatin and Chemoradiation for 6-8 weeks. After completion randomisation will be done. Half will receive adjuvant Carboplatin and the other half will be observaved as is the stand of care.
If controlled, specify the comparator	
Other medicinal product(s)	No
Placebo	No

Other	No
If yes to other, specify	
Other	Yes

Expected Number of participants in Zimbabwe *	60
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	60
Total participants worldwide *	120

Time period for the trial *	5 years (3 years of recruitment and 2 year of follow-up)