Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	Thermal Ablation Study
Scientific Title	Evaluation of the acceptability, safety and effectiveness of thermal ablation in the prevention of cervical neoplasia in Zimbabwe

Primary Sponsor Details

Sponsors *	International Agency for Research on Cancer

Secondary Sponsor Details

Contact for Public Queries

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Affiliation	University of Zimbabwe College of Health Sciences Clini

Contact for Scientific Queries

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Countries of Recruitment *

Zimbabwe

Source of Funds	International Agency for Research on Cancer
Health Condition(s) or Problem(s) Studied *	Cervical Cancer
Medicine Name *	Lignocaine
Quantity of medicine required *	4 mls per participant

7.0 PRINCIPAL INCLUSION CRITERIA *

Clinically healthy women aged 25-59 years, not pregnant, (a pregnancy test will be carried out) with an intact uterus and with no history of debilitating physical and mental illness (a disease that makes one very weak and unable to function) and who satisfy all the following criteria, are eligible to participate in the study:

1. Screen positive women with colposcopically suspected high-grade lesions (CIN 2/3) fulfilling the eligibility criteria for ablative treatment. Biopsies will be obtained from the cervical lesion(s) prior to treatment and the results will be reviewed post-treatment.

2. Women with histopathologically confirmed CIN 2/3 fulfilling the eligibility criteria for ablative treatment.

3. Women provide informed consent voluntarily

7.1 PRINCIPAL EXCLUSION CRITERIA *

1. Age < 25 years or > 59 years

2. Pregancy test positive

3. Debilitating physical or mental illness

4. Cervical cancer screen test negative

5. Histology is normal or shows low-grade lesions (CIN 1)

6. Declines to give consent

7.2 PRIMARY END POINTS *

1. Pain control with lignocaine

2. Cure rate at 12 months

3. Residual/persistent disease at 12 months

9.0 DESIGN OF THE TRIAL

Type of trial *	Controlled
If controlled	
Randomised	Yes
Single Blind	No
Double Blind	No
Parallel group	No
Cross over	No
Other	No
If yes to other, specify	
If controlled, specify the comparator	
Other medicinal product(s)	No
Placebo	No
Other	No
If yes to other, specify	
Other	No

Expected Number of participants in Zimbabwe *	184

Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	
Total participants worldwide *	

Time period for the trial * 3 years