



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

Name * Dr Bothwell Guzha

Designation * Principal Investigator

Email * bothwellguzha@gmail.com

Phone number * 0772287143

Postal Address* 15 Phillips Avenue Belgravia harare

Affiliation University of Zimbabwe College of Health Sciences Clini

Contact for Scientific Queries

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Affiliation University of Zimbabwe College of Health Sciences Clini

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. Pregnancy 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