PIOGLITAZONE-METFORMIN COMBINATION TREATMENT FOR HIGH RISK ORAL PRENEOPLASIA

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- hyperplasia in high risk areas (floor of mouth, mobile tongue, oropharynx) confirmed by biopsy - able to swallow a tablet whole - Body mass index (BMI) is ≥ 18.5 - sexually active persons of child-bearing potential agrees to use adequate contraception - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- women who are pregnant or breastfeeding or planning to become pregnant - diagnosis of Type I or Type II diabetes that is being treated with insulin or an antidiabetic agent - history of bladder cancer, including in situ bladder cancer - history of invasive cancer (other than non-melanoma skin cancer or cervical cancer in situ) in past 18 months - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Drug: pioglitazone-metformin
Conditions:
Cancer, Community Health
Keywords:
Clinics and Surgery Center (CSC), Oral Leukoplakia

More Information

Description: The purpose of this study is to learn about the safety and effects of pioglitazone and metformin on people and their risk of cancers of the head or neck. We hope to learn more about the potential for pioglitazone and metformin to be used as a way to prevent oral or oropharyngeal cancers in people who are at risk for those cancers. Participants will get both pioglitazone and metformin, as a single pill to be taken at the same time for 12 weeks.
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Phase: PHASE2
IRB Number: SITE00001771

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