

# COMBINING LONG-LASTING INSECTICIDAL NETS AND INDOOR

# RESIDUAL SPRAYING FOR MALARIA PREVENTION IN ETHIOPIA: STUDY

# PROTOCOL FOR A CLUSTER RANDOMIZED CONTROLLED TRIAL

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#### INTRODUCTION

- Long-lasting insecticidal nets (LLINs) and indoor residual spraying (IRS) are the two main malaria prevention strategies in Ethiopia
- Although both interventions have been shown to be effective in reducing malaria transmission when applied independently, there is no strong evidence that either one or the two in combination is better than the other.
- Evidence about the added value of IRS when combined with LLINs is scarce

#### RESEARCH QUESTIONS

- Can the combined use of LLINs and IRS significantly reduce malaria incidence compared with the use of either LLIN or IRS alone?
- Is the reduced incidence justifiably compared to the added costs?
- Will LLINs+IRS reduce vector density, longevity, behaviour and the entomological inoculation rates (EIR) compared to single interventions?

#### RESEARCH HYPOTHESIS

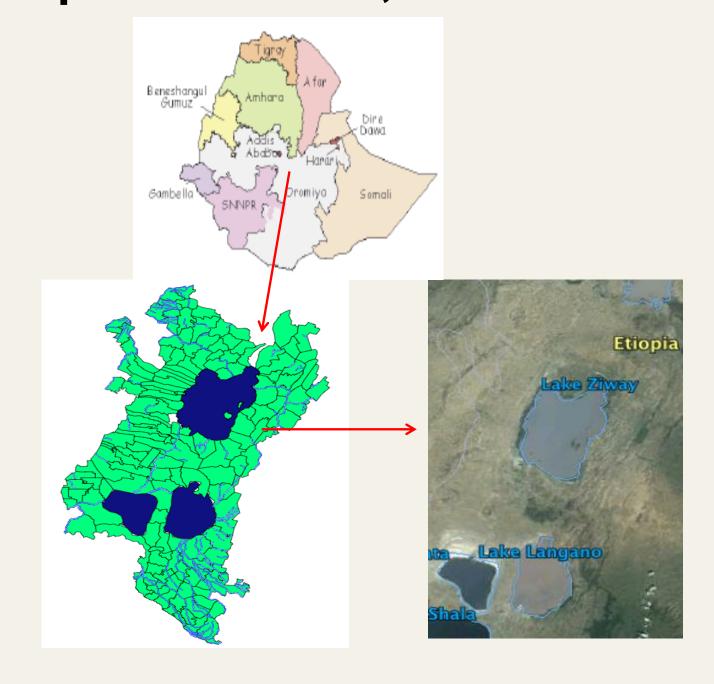
- LLINs+IRS would result in a 25% reduction in malaria incidence compared with the use of LLINs alone
- IRS+LLINs will increase hemoglobin level among children by 0.5 mg/ml compared with LLINs alone

## **OBJECTIVES**

- Examine if IRS+LLINs provide added protection against malaria compared with either IRS or LLINs alone
- Assess whether IRS+LLINs reduces anaemia and parasite prevalence compared with LLIN/IRS alone
- Estimate the costs of LLINs/IRS alone or IRS+LLINs, compared to current standard practice in the study settings, and to calculate incremental costs, incremental effects and cost-effectiveness of the intervention arms
- To assess whether IRS+LLINs reduces human biting rates, resting density, longevity, sporozoite rates, and EIR compared with IRS/LLINs alone

#### MATERIALS AND METHODS

- This trial will be conducted in Adami
   Tullu district of Oromia Regional
   State in Ethiopia from 2013 to 2016
- Population: ≈150,000



• A cluster randomized controlled trial, with four "arms" (factorial design):

	IRS (Yes)	IRS (No)
LLINs (Yes)	A	В
LLINs (No)	С	D

 The sample size includes 40 clusters in each arm, each cluster with 35-45 households (About 1750 households in each arm).

#### INTERVENTIONS

- LLINs and IRS
- All households in the IRS+LLINs and LLINs alone "arms" of the study will be provided new LLINs free of charge.
- IRS with an insecticide propoxur will be applied in IRS+LLINs and IRS alone arms twice a year throughout the study.

# PRIMARY OUTCOME MEASURE

Detection of malaria parasites (*P. falciparum* or *P. vivax*) by RDTs and microscopic blood slide examination

## SECONDARY OUTCOME MEASURES

- Incidence of malaria
- Proportion of malaria infections attributable to the different Plasmodium species
- Prevalence of anaemia among <5 children</li>
- Entomological outcome measures such as EIR
- Cost of interventions
- Number of malaria cases averted and death prevented

#### DATA COLLECTION

- Each household will be weekly visited, and clinical history and blood sampling will be performed on each member of the household with fever or history of fever
- Thick and thin blood smears will be collected using RDTs will be used to detect malaria at field level.
- Data on all self-reporting malaria patients will be collected from health posts
- Blood sample will be collected from all <5 children after peak malaria to determine haemoglobin level
- Cost-effectiveness & entomological studies will be conducted
- Analysis will be based on intention to treat principle
- Ethical clearance was obtained from the Ethiopian Ministry of Science and Technology and Rek Vest in Norway
- Informed consent will be sought from all households and study participants

#### DISCUSSION

- The trial aims to provide evidence on the combined use of IRS+LLINs for malaria prevention.
- It aims to answer the following research questions: Can the combined use of LLINs+IRS significantly reduce malaria incidence compared with the use of LLINs or IRS alone?
- And is the reduced incidence justifiably compared to the added costs?
- Will the combined use of LLINs+IRS reduce vector density, infection, longevity and EIR?
- Such data is crucial in order to maximize the impact of the intervention on malaria.

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