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Comparing a mosquito control intervention to standard community information to reduce the incidence of Buruli ulcer

Submission date
16/12/2018

Recruitment status
Suspended

Registration date
11/01/2019

Overall study status
Completed

Last Edited
17/04/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Buruli ulcer (BU) is an invasive lesion caused by infection with Mycobacterium ulcerans (M. ulcerans) bacteria. Mosquito bites may be important for spreading M. ulcerans to humans, causing BU. We aim to compare the usefulness of a mosquito control program with standard community information for the reduction of BU in the Mornington Peninsula, Victoria. We are using a cluster randomized controlled trial to investigate this.

Who can participate?
All residents living in the study area.

What does the study involve?
Mosquito surveillance traps will be set up in variety of locations in the study area. Community information about how people can protect themselves from mosquito bites, and in doing so possibly reduce their risk of getting BU, will be delivered as a leaflet in people's letterboxes. Small areas ('clusters') that have randomly been allocated to receive the mosquito control program (the intervention) will have intensive pesticide delivery in public areas in accordance with usual public health protocols used by the Victorian Department of Health and Human Services (DHHS). In addition, residents of intervention areas will have a second leaflet delivered to their letterboxes. This leaflet will explain that mosquito control activities will occur in their neighbourhood (in advance) and will let residents know that they are able to buy mosquito traps and larvicide from the local council for use at their home if desired. The leaflets will include information about who to contact, and how, if there are any questions or concerns that people would like to discuss. The Victorian Arbovirus Disease Program Manager (DHHS) will oversee these processes.

What are the possible benefits and risks of participating?
Possible benefits include an increased awareness of Buruli ulcer, increased awareness of how to avoid being bitten by mosquitoes, decreased risk of Buruli ulcer.

Possible risks include an extremely low likelihood of people or animals suffering ill health effects due to pesticide exposure. Synthetic pyrethroid pesticides (SP) have been used widely in public health mosquito control activities. Adverse health effects following SP use in outdoor areas has not been reported when the pesticide is administered appropriately. There is a risk of collateral damage to other insect populations occurring – but we will encourage beekeepers to contact us to ensure no beehives are accidentally treated. It is very unlikely that animals which eat mosquitoes will experience a reduction in food stocks as our intervention is not likely to decimate the mosquito population and no animal populations in the study area rely solely on mosquitoes as a food source. There is a risk that people will be worried about their risk of Buruli ulcer or of adverse effects due to pesticide use. There is a risk that people will feel inconvenienced by fogging trucks on the road or by setting up mosquito traps.

Where is the study run from?
The University of Melbourne and the Victorian Department of Health and Human Services.

When is the study starting and how long is it expected to run for?
October 2018 to June 2021

Who is funding the study?
The National Health and Medical Research Council, the Victorian Department of Health and Human Services, Mornington Peninsula Shire Council.

Who is the main contact?
Dr Jane Oliver
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
2.3

Study information

Scientific Title
A partially-blinded cluster randomized controlled, superiority trial to compare a multi-factorial mosquito control intervention to standard community information for the reduction of Buruli ulcer in the Mornington Peninsula, Victoria, Australia

Acronym
BUIS

Study objectives
Implementation of a geographically targeted, multi-factorial mosquito control program will reduce the incidence of Buruli ulcer among residents of intervention areas compared to residents of control areas who receive standard community information about mosquito control and Buruli ulcer prevention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/02/2019, Victorian Department of Health and Human Services (DHHS) Human Research Ethics Committee (50 Lonsdale Street, Melbourne, Victoria, Australia, 3000; Tel: +61 (0) 1300 650 172), ref: HREC/47520

Study design
Partially-blinded cluster randomized controlled superiority trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Buruli ulcer

Interventions

The study area comprises 76 small area clusters lying within the Rosebud-Portsea region of the Mornington Peninsula, Victoria, Australia. Clusters are generated by randomly allocating combinations of mesh blocks that shared a border, until a condition on the size of the cluster is met (ie. 225 individual residents per cluster; the number required to achieve sufficient statistical power (80%) to detect a significant difference in the primary outcome measure). Clusters are matched in pairs. Pairs are made based on clusters having similar incidence rates of Buruli ulcer in recent years. One cluster from each pair is randomly selected to receive the intervention (ie. the mosquito control program), while the other is assigned to control status. Randomization is conducted using code written in the statistical software package R.

Residents of the entire study area (regardless of whether they live in a control or an intervention cluster) will receive information about how to protect themselves from mosquito bites, for example by wearing protective clothing, and in doing so possibly reduce their risk of developing Buruli ulcer. This information will be delivered once as a leaflet letterbox drop in mid-late Spring (Oct-Nov) of 2019.

Mosquito control program: This is a multifactorial program intended to reduce the mosquito population. It will be applied to intervention clusters, while control clusters will receive the leaflet about mosquito bites and Buruli ulcer prevention only. A letterbox leaflet drop will occur just before the start of the mosquito breeding season in intervention clusters, informing residents of the mosquito control activities taking place in their neighbourhoods, and letting them know that they are also able to purchase mosquito traps and larvacide at cost-price for home use from the local Council. The mosquito control program involves residual harbourage spraying of vegetation in Council-owned outdoor areas using synthetic pyrethroid pesticide (SP) every 4-6 weeks during the mosquito breeding season (Dec 2019 - Apr 2020). At the time of spraying, larvacide will also be placed into public water sources considered likely to provide a suitable habitat for mosquito larvae. In addition, when adult mosquito numbers reach a pre-determined high level (as identified using mosquito surveillance traps), fogging (using SP) will be conducted to instantly reduce the adult mosquito population. We expect to conduct fogging 1-4 times during the mosquito breeding season. Trained pesticide administrators who are employed /contracted by the Victorian Department of Health and Human Services (DHHS) will perform these activities in accordance with usual DHHS protocols, with oversight from the Victorian Arbovirus Disease Control Program Manager.

As several months may pass between the first signs of Buruli ulcer appearing and the case being notified to public health authorities, we will continue to collect notification data (with residential address information) on Buruli ulcer cases up until 31 Dec 2020 in order to reduce our likelihood of missing cases.

Intervention Type
Mixed

Primary outcome(s)
The incidence rate of Buruli ulcer in intervention areas compared with the incidence rate in control areas for the period 1 Dec 2019 - 31 Dec 2020. When calculating the incidence rate in intervention areas, the numerator is the count of notified Buruli ulcer cases whose residential addresses lie in an intervention cluster. The denominator is the estimated resident population of the intervention area, which is obtained from the Australian Bureau of Statistics. The incidence rate for control areas is calculated in the same way using corresponding data.

Key secondary outcome(s))

1. Count of trapped mosquitoes captured in intervention areas compared with the count of trapped mosquitoes captured in control areas using mosquito surveillance traps over the period 1 Dec 2019 – 30 Apr 2020.
2. Count of Buruli ulcer cases linked to intervention areas compared to the count of cases linked to control areas over the period 1 Dec 2019 – 31 Dec 2020. 'Linked' is defined as a case either having a residential address in the intervention/control area, or having visited one such area and stayed there for at least one night at the time symptoms of Buruli ulcer first appeared. This information is provided in the case notification data.
3. To quantify by PCR the concentration of M. ulcerans in different species of trapped mosquitoes at selected sites, both in control and intervention areas on the Mornington Peninsula, over the period 1 Dec 2019 – 30 Apr 2020. Mosquito species will be determined by entomologists.

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Resident of a control or intervention area.
2. Visitor to a control or intervention area.

Participant type(s)
All

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Do not reside in control or intervention areas
2. Did not visit these areas and develop Buruli ulcer during the study period.

Date of first enrolment
01/12/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Australia

Study participating centre
Portsea
Melbourne
Australia
3944

Study participating centre
Sorrento
Melbourne
Australia
3943

Study participating centre
Blairgowrie
Melbourne
Australia
3942

Study participating centre
Rye
Melbourne
Australia
3941

Study participating centre
Tootgarook
Melbourne
Australia
3941

Study participating centre
St Andrews Beach
Melbourne
Australia
3941

Study participating centre

Fingal
Melbourne
Australia
3939

Study participating centre
Boneo
Melbourne
Australia
3939

Sponsor information

Organisation
University of Melbourne

ROR
https://ror.org/01ej9dk98

Funder(s)

Funder type
Government

Funder Name
National Health and Medical Research Council (Australia)

Alternative Name(s)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Funder Name
Department of Health, State Government of Victoria

Alternative Name(s)
Victorian Department of Health, Department of Health, Victorian State Government

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Australia

Funder Name
Mornington Peninsula Shire (Australia)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the need to protect the privacy of individuals involves in the study, some of whom will have had Buruli ulcer.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes