

FINAL DRAFT

Two New Leprosy Skin Test Antigens: MLSA-LAM and MLCwA Phase II Study in a Leprosy-Endemic Region

Part C1

DMID Protocol #00-002

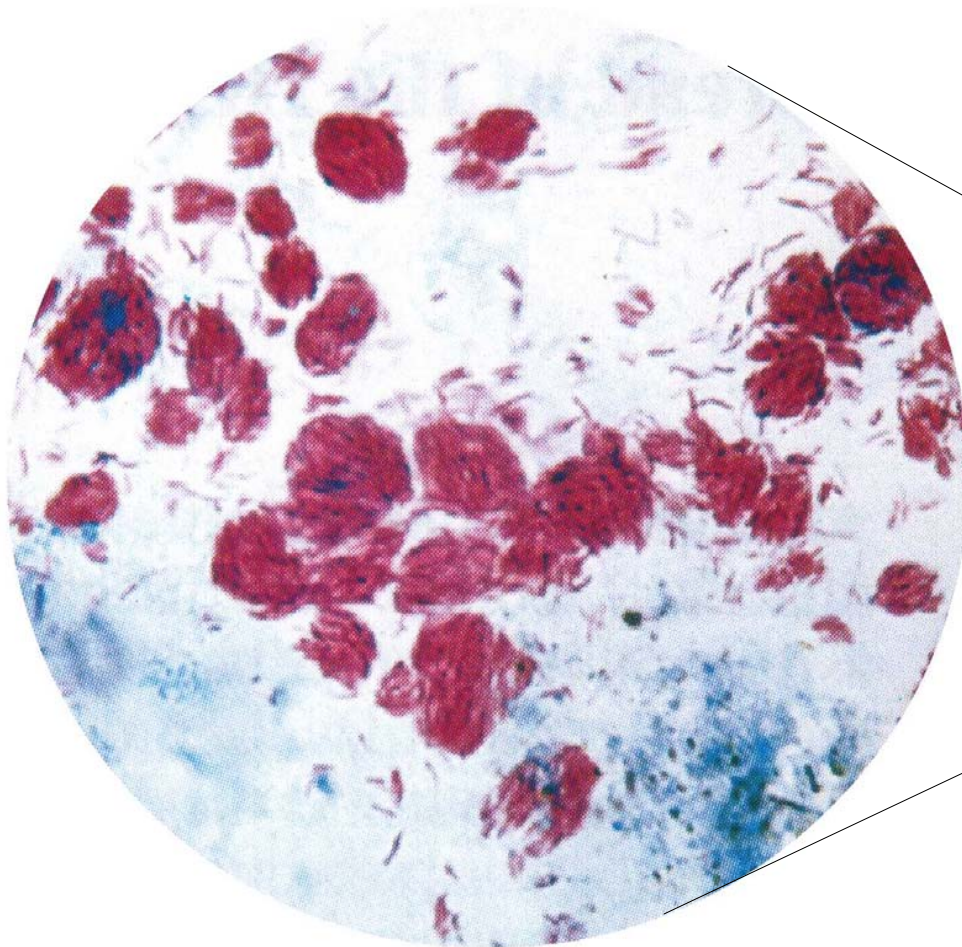
**Anandaban Hospital, The Leprosy Mission Nepal
Kathmandu, Nepal**

**Department of Microbiology, Colorado State University
Fort Collins, Colorado, USA**

Introduction

- Caused by a germ, a type of bacteria called *Mycobacterium leprae*, (similar to the TB germ)
- Clinical signs:
 - White spot on the skin with no feeling when touched
 - Some with enlarged nerves, (sometimes painful)
 - Thickening of skin on face, earlobes (“Buddha-ear”)
 - Tingling sensation in some parts of the body

The Leprosy Bacteria



Leprosy is not always easy to diagnose

- Reasons for late diagnosis:
 - Symptoms in the early stage not easily recognized
 - People try to hide their illness (social stigma)
- Disadvantages of late treatment:
 - Nerve death = disabilities / deformities
- Spread of the disease is not clear:
 - Direct contact
 - Through the respiratory system (droplet infection)

Skin Test Study

- **The study:**
 - Two new skin tests (injections)
 - Made in the US using bacterial parts
 - Safety studies in the US and Nepal showed it is safe for human use
- **Need for this injection (Purpose):**
 - Test new tool for early detection of leprosy infection
 - No other definitive diagnostic test presently in use
 - Test in area where there is more leprosy (in endemic region)

Study Progress up to the Present

- The study is divided into three parts
- Part A & B (completed in Jan 2004 successfully):
 - 100 healthy non-contact volunteers in Nepal injected with the new skin tests
 - No major side effects or illness directly related to the new skin tests were observed.
- Part C:
 - Leprosy Patients - 147 individuals
 - Healthy Contacts - 140 individuals
 - Healthy Non-contacts - 90 individuals
 - TB Patients - 40 individuals

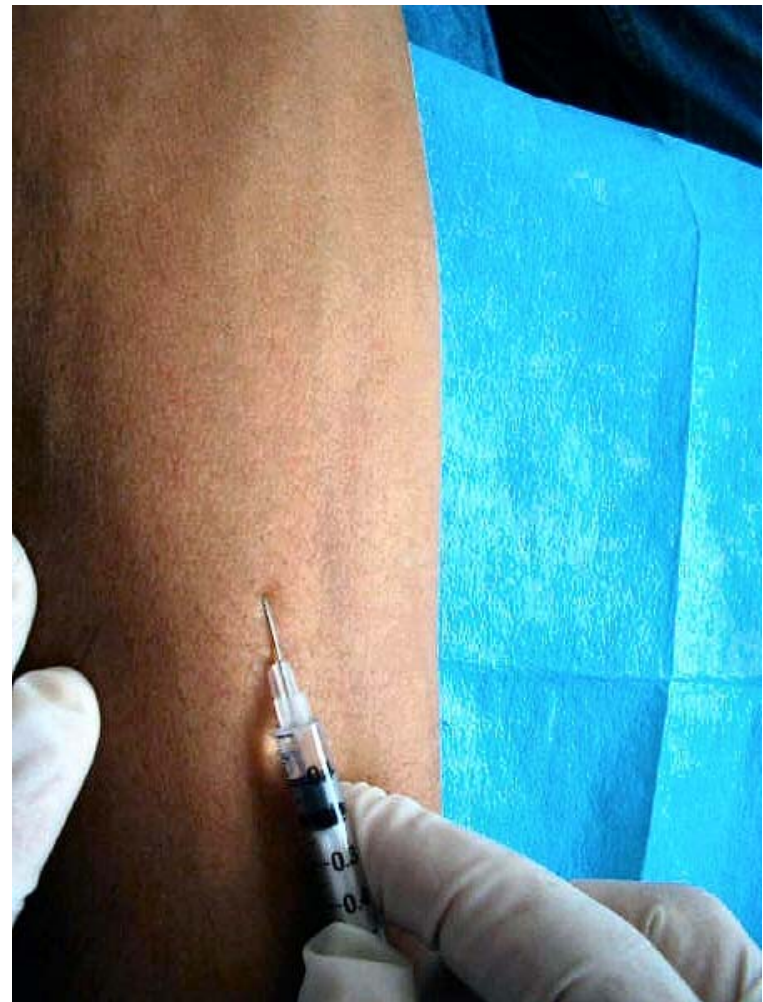
Procedures

- All volunteers will have physical examination before injections:
 - All women volunteers will have a urine test for pregnancy
- Blood examination will also be done:
 - It will tested if it has natural substances that can kill or limit the bacteria



Procedure for Injections

- Each volunteer will get 3 injections:
 - 2 injections of the leprosy test
 - 1 injection of the usual test for TB



Injections (where it is given)



- two injections on forearm of below the elbow of one arm and one on the other arm below the elbow

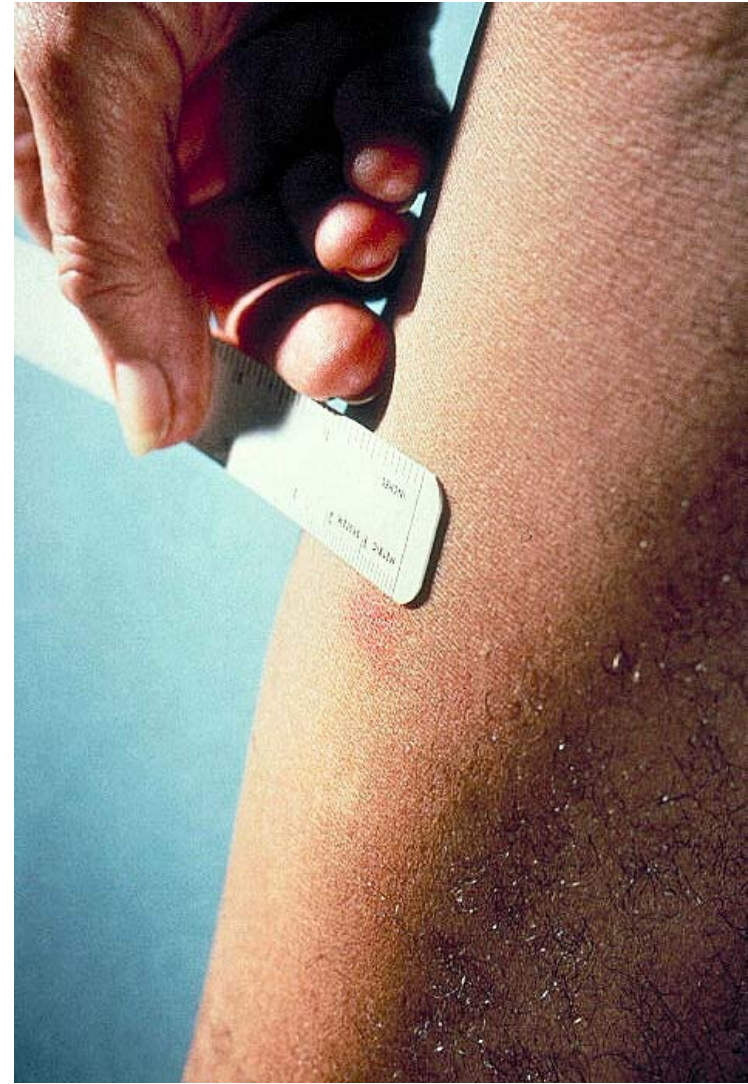


- 2 to 3 days after injection, a small swelling like a mosquito bite may develop around some or all of these

Examination after Injections

- 15 minutes after the injection
- After 3 days
- After 7 days
- After 28 days

If you have any problem or reaction due to the injection we may ask you for additional examination visits.



Additional Information

- This Test:
 - Is for research only at this time and not yet permitted for general use
 - Will not indicate that you have leprosy
 - Will not indicate that you will be in danger of contracting leprosy
 - Will not contract leprosy from this test

If...

- it is found that you have leprosy, Anandaban Hospital will provide free treatment
- it is found that you have tuberculosis, you will be referred to a related hospital for treatment.

Risks & Benefits to the Volunteer

- Risk from injections is small
- Infection around the injection site for some
 - Those who show signs will be given antibiotics to prevent this
- Allergic reaction for some
- Safety precautions
 - Emergency equipment & medicines
 - Coordination with hospital emergency services
- Indirect help
 - Your participation can indirectly help others in the community

Confidentiality

- Results of this study will be published but your name or identity will not be made known
- Your records may be reviewed by ...
 - Colorado State University
 - United States Food & Drug Administration
 - The sponsor of this study:
 - National Institutes of Health
 - Nepal Health Research Council

Voluntary Participation

- Your participation in this study is voluntary
- You may withdraw from this study of your own free will at any time without penalty
- You agree to give some blood and receive the injections as outlined above and allow the examination of the injection site
- You have heard and understood the information above and sign the form willingly.

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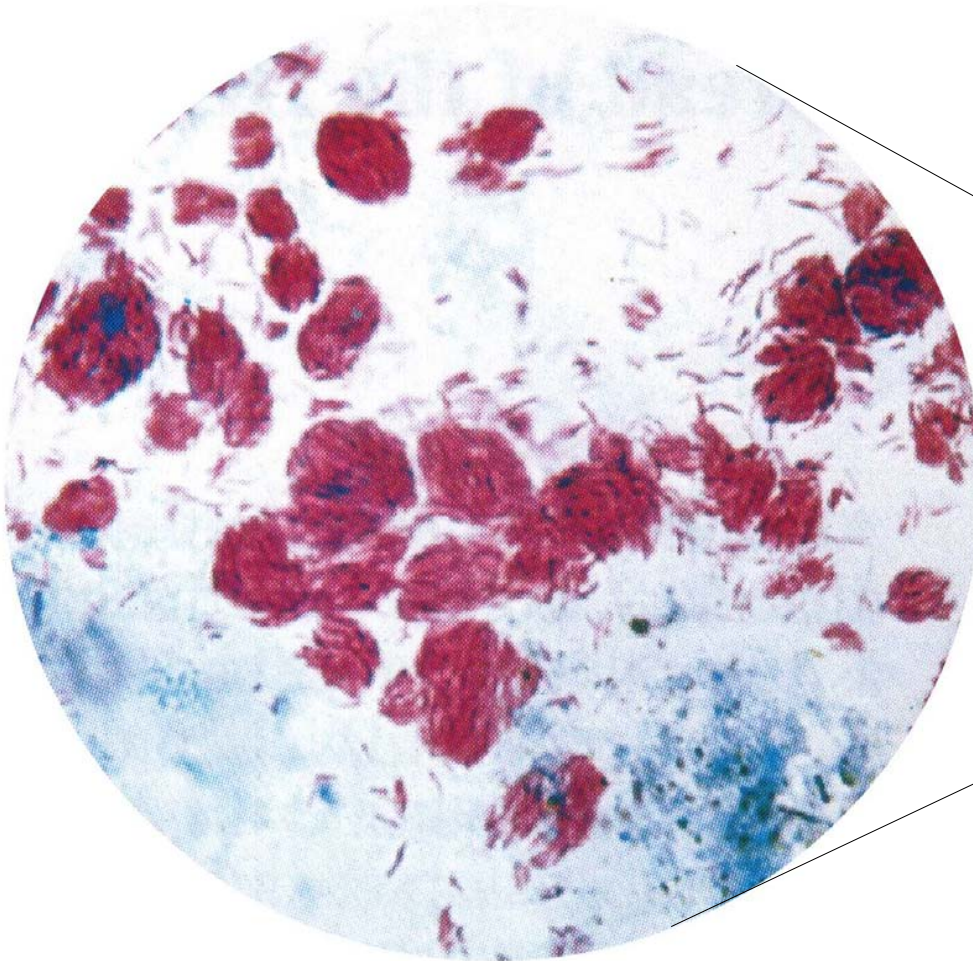
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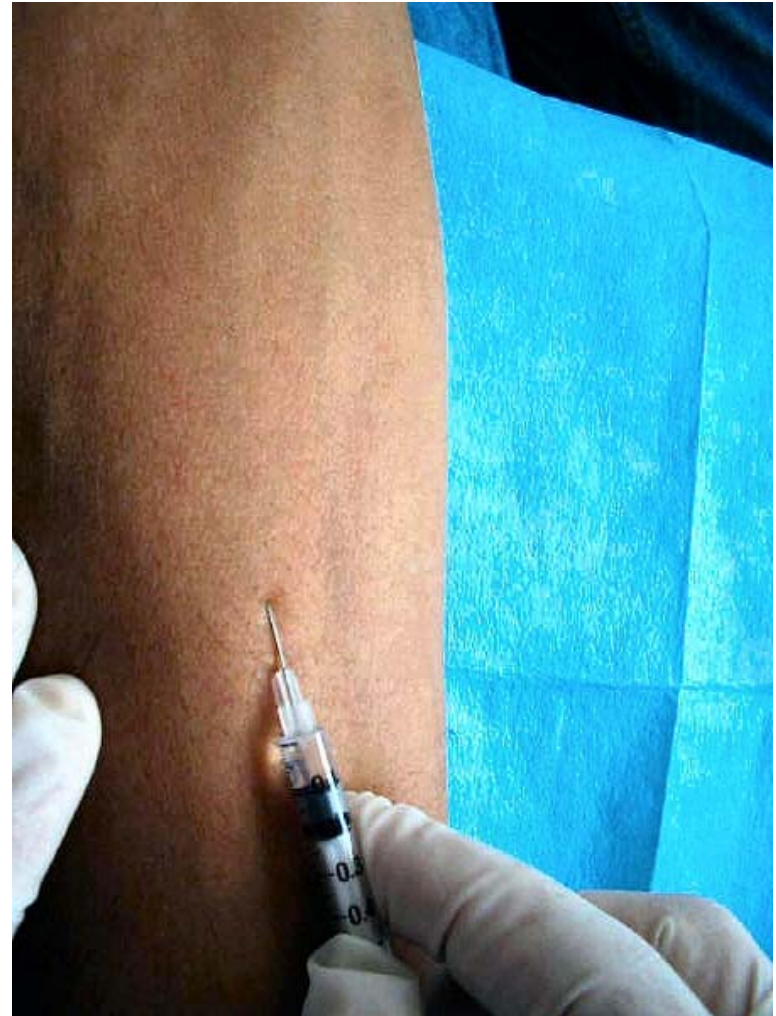
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 - Is for research only at this time and not yet permitted for general use
 - Will not indicate that you have leprosy
 - Will not indicate that you will be in danger of contracting leprosy
 - Will not contract leprosy from this test
- If...
 - it is found that you have tuberculosis, you will be referred to a related hospital for treatment.

Risks & Benefits to Volunteer

- This is the first time this test is being given to people with leprosy. The swelling and itching seen in people without leprosy was small. Because you have leprosy, the swelling may be bigger than was in the picture.
- Infection around the injection site for some
 - Those who show signs will be given antibiotics to prevent this

Risks & Benefits to Volunteer (cont'd)

- Allergic reaction for some
- Safety precautions
 - Emergency equipment & medicines
 - Coordination with hospital emergency services
- The risk from injections is small
- Indirect help
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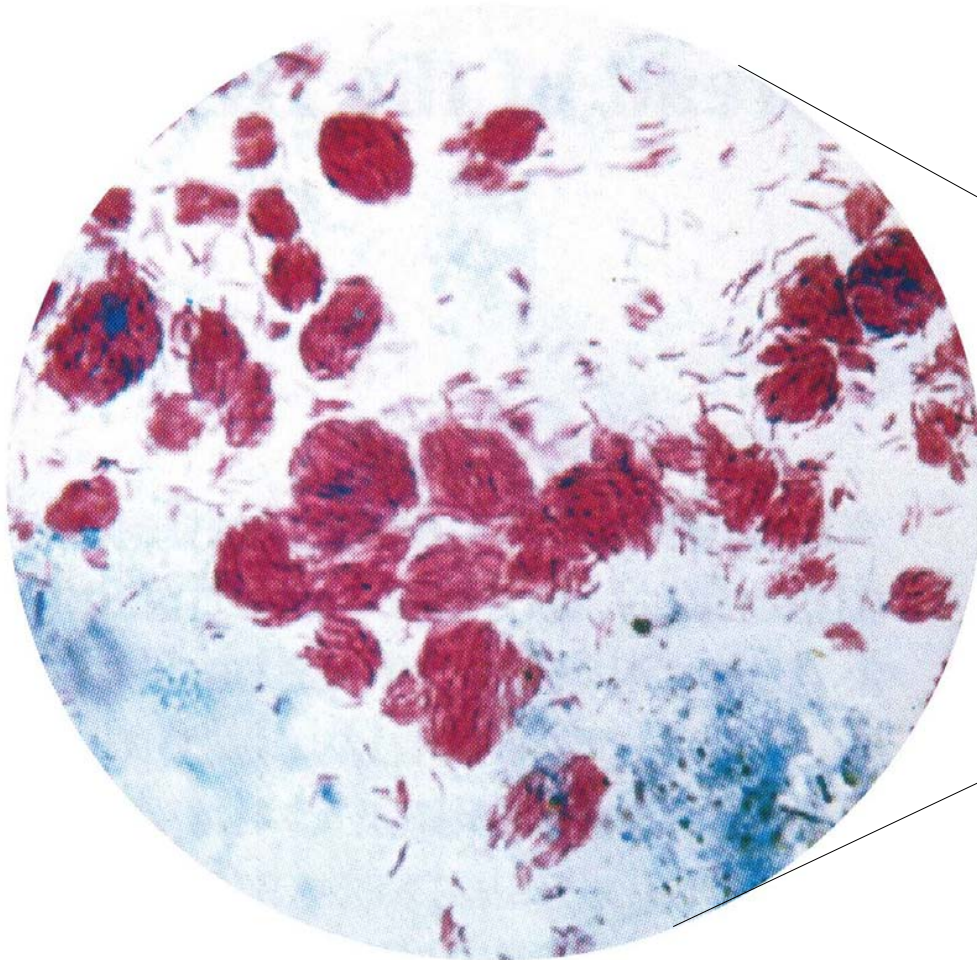
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The Leprosy Bacteria



Leprosy is curable

Before
MDT

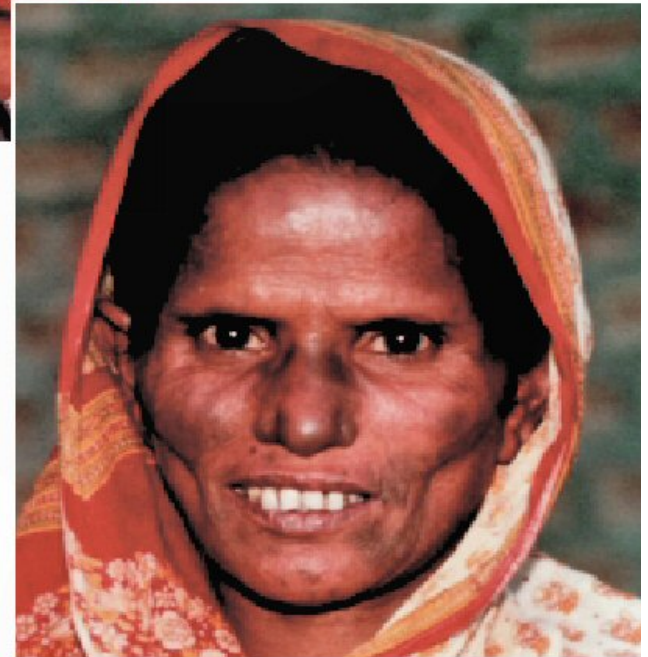


Before
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Procedures

- One of the people who lives in the same house as you has been asked to participate in this study
- If they agree to participate, we will need to look at your medical records to get some information about you.
- We will need your permission to look at your medical chart.

Procedures (cont'd)

- We need to get the following information from your chart:
 - Hospital number
 - Hospital where you were treated
 - Leprosy type
 - Initial skin smear result
 - Treatment history
 - Months of treatment
 - Whether released from treatment
- We will also ask the person how long they have lived in the same house as you.

Risks & Benefits to Volunteer

- No direct benefit to participating in the study
- Indirect benefit
 - Information gained about early detection of individuals infected with leprosy should be helpful to others with leprosy or exposed to leprosy

Confidentiality

- Results of this study will be published but your name or identity will not be made known
- Your records may be reviewed by ...
 - Colorado State University
 - United States Food & Drug Administration
 - The sponsor of this study:
 - National Institutes of Health
 - Nepal health Research Council

Voluntary Participation

- Your participation in this study is voluntary
- You are free to decide not to allow us to look at your medical records to obtain the above information.
- You have heard and understood the information above and sign the form willingly.