To assess the efficacy of SA4Ag in the prevention of postoperative S. aureus blood stream infection (BSI) and/or deep incisional or organ/space surgical-site infection (SSI) within 90 days of elective open posterior spinal fusion procedures with multilevel instrumentation, in adults aged 18 to <86 years.

**Study Design**

- 2600 patients expected to accumulate 42 per-protocol 'cases' within 90 days of index surgery
- Multicenter, double-blind, randomized, placebo-controlled
- Subject participation 6 to 8 months
- Evaluations: efficacy, safety, tolerability, immunogenicity, SA colonization

**Ideal sites**

To meet recruitment target, ideal site must have:

- Access to potential subjects to meet recruitment goals (4-5 subjects/month).
- Patients undergoing elective open posterior spinal fusion procedures with multilevel instrumentation.
- Study research personnel capable of:
  - Following patients daily during hospitalization.
  - Obtaining third party medical records.
  - Performing weekend visits if needed.
- Most sites are large academic institutions led by either neurosurgeon or orthopedic surgeon.

**Data Monitoring Committee**

- DMC responsible for:
  - Assessing safety data throughout the study.
  - Assessing vaccine futility/efficacy against S. aureus disease at the interim analysis.
- Unblinded data will be provided by an Independent Statistical Team (IST) to enable the DMC to make assessments and recommendations.

**Additional Recruitment Activities**

- Recruitment assistants.
- App referral system.
- Website: strivestudy.com

**Posters & Contact Pads**

- Brochures provide a study summary to take home and review in a more comfortable setting.
- Brochures have a contact info area that can be customized with specific site and contact information.

**Primary Objective**

To assess the efficacy of SA4Ag in the prevention of postoperative S. aureus blood stream infection (BSI) and/or deep incisional or organ/space surgical-site infection (SSI) within 90 days of elective open posterior spinal fusion procedures with multilevel instrumentation, in adults aged 18 to <86 years.

**Elective Open Posterior Spinal Fusion with Multilevel Instrumentation Procedure**

'Spinal fusion' is defined as a surgical arthrodesis procedure.

**Protocol Defined Infections (PDI)**

- PDI clinical criteria utilize NHSN surveillance criteria.
- Blood stream infections (BSI)
- Deep incisional SSI
- Organ/Space SSI
- Superficial SSI
- Invasive S. aureus (ISA)

**Scheduled Study Visits**

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<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
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<td>Day 1</td>
<td>Day 2</td>
<td>Day 21</td>
<td>Day 42</td>
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**Additional Recruitment Activities**

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**Protocol Defined Infections (PDI)**

- PDI clinical criteria utilize NHSN surveillance criteria.
- Blood stream infections (BSI)
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**Efficacy and Safety Event Adjudication & Decision Flow Overview**

**Data Monitoring Committee**

- DMC responsible for:
  - Assessing safety data throughout the study.
  - Assessing vaccine futility/efficacy against S. aureus disease at the interim analysis.
- Unblinded data will be provided by an Independent Statistical Team (IST) to enable the DMC to make assessments and recommendations.

**Patient Reminders**

How mPal works: At a glance

**Recruitment Materials**

- Posters provide a synopsis of the study and refer interested subjects.
- Contact pads are customized with site’s contact information. They can be used as an attachment to the posters.

**Study Site**

- Recruitment assistants.
- App referral system.
- Website: strivestudy.com