Screening & Baseline Assessment  
\( n=2356 \)

Informed Consent

Enrolment

Randomisation

Exclusion Criteria
- History of hospitalization to allergic reaction
- Not meeting inclusion criteria due to presence of caries
- Refused to consent

Allocated to test group (\( n=600 \))
Preventive package fluoride varnish and fluoride toothpaste plus standardized health education

Six x Six-monthly visits to dentist for
- Allocated Treatment
- Adverse events
- Costs
Final visit
- Outcome assessment

Primary Outcome
- Presence of Dental Caries
- Secondary Outcomes
- Number of carious teeth
- Adverse events
- Costs

Allocated to control group (\( n=600 \))
Standardized health education only

Six x Six-monthly visits to dentist
- Allocated Treatment
- Adverse events
- Costs
Final visit
- Outcome assessment

Primary Outcome
- Presence of Dental Caries
- Secondary Outcomes
- Number of carious teeth
- Adverse events
- Costs

Treatment Allocation

Follow-Up

Intention to Treat Analysis