Amish Silver Nitrate Clinical Trial: Study Design and Subject Recruitment

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Funding

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- Dow’s Institute for Dental Research
- Department of Pediatric Dentistry
Purpose of the Study

To compare the conventional approach of restoring caries in the primary dentition, to medically managing caries using silver nitrate and fluoride varnish.
Study Population

- Amish children living in Kalona, IA.
- Settlement established 1845
- Ave. family has 8 children
- High caries rate
- Low exposure to fluoride
- Limited access and utilization of regular dental care
Study Design

• Randomized controlled clinical trial.
• Inclusion Criteria:
  – Healthy children (2-11 years of age) with at least one primary tooth with caries into dentine.
• Random assignment to one of two groups:
  – Conventional restorative group
  – Silver nitrate / fluoride varnish group
• Subjects to be followed for a minimum of two years
Study Teeth

- Prior to random assignment, a clinical exam was done to determine which teeth would receive treatment.
- Decision to Treat – if conventional treatment without pulp therapy was not an option for a carious primary tooth, the tooth was excluded from the study:
  - Tooth going to exfoliate soon
  - Signs or symptoms of irreversible pulpitis indicating caries into pulp needing pulp therapy or extraction.
Conventional Group

- Exams and radiographs
- Oral Health Education
- Prophy
- Fluoride Varnish application
- Restorations for caries into dentine
  - Composites
  - Stainless Steel Crowns
  - No amalgams
- 6 – month recall schedule with BW radiographs

Silver Nitrate Group

- Exams and radiographs
- Oral Health Education
- Prophy
- 3 Silver Nitrate applications, 1 month apart
- Fluoride Varnish application
- 6 – month recall schedule with BW radiographs
Silver Nitrate Application

- 5 second application per carious lesion
- Immediately cover with fluoride varnish
- Nothing to eat or drink for 30 minutes
- Accessible lesions (open cavities and facial/lingual smooth surface lesions
  - Apply silver nitrate with microfiber brush
- Interproximal lesions
  - Apply silver nitrate with super-floss or G.U.M soft-pick
Interproximal application
Outcome Measures

- Caries incidence and progression (arresting)
  - Patient level
  - Tooth level
- Major and minor failures (study teeth)
- Patient quality of life
- Cost-effectiveness
- Acceptability of treatment strategies to patients, and parents.
Subject Recruitment

- IRB requirements for cultural competency
- Letter of support from Amish Community
- All written materials to be reviewed and deemed appropriate/acceptable by someone with Amish ties
Current Progress of the Study

- Oct, 2014 – IRB approval (201406792)
- Oct & Nov, 2014 – Informational sessions
- July, 2015 – Recalls began
Assessed for Eligibility = 83

Excluded = 19

Randomized = 64

Silver Nitrate
45 Subjects
214 Teeth

Did not receive intervention = 0

Received Intervention = 45

Discontinued Intervention = 0

Lost to Follow-Up = 0

Followed Up = 30/45

Not Analyzed = 45

Analyzied = 0

Conventional
19 Subjects
65 Teeth

Did not receive intervention = 0

Received Intervention = 19

Discontinued intervention = 0

Lost to Follow-Up = 0

Followed Up = 15/19

Not Analyzed = 19

Analyzied = 0

77%
Next Steps

- Would like to have 90 children enrolled in study
- Continue to follow
- Analyze data
Questions?