

Ancillary benefits of running a cluster randomised control trial in Eastern Uganda

Ravi Lad, Ediri O'Brien, David Mukunya, Martin Chebet, Kathy Burgoine, Brian Faragher, Melf-Jakob Kühl, Duolao Wang, Antonieta Medina-Lara, Ingunn Marie Stadskleiv Engebretsen, Thorkild Tylleskar, Andrew D Weeks, and BabyGel Study Group

Introduction

The BabyGel Study was a large cluster-randomised controlled trial assessing whether alcohol-based hand rub (ABHR) could reduce infant sepsis and death among 6102 mother-child pairs from 34 weeks gestation to 3 months postpartum in rural Eastern Uganda. Conducted across 72 villages and funded by EDCTP2 (€5.9M), the study aimed to generate evidence on Water, Sanitation, and Hygiene interventions' impact on child health in low-income settings. It also highlights the critical need for more clinical research in low-income countries (Toto et al., 2020), where trial registration remains drastically lower than in high-income countries (WHO, 2024).

BabyGel ensured that the next clinical research projects have a foundation to which build upon. *"Bridging the Global Research Gap"*



Local Engagement & Impact Highlights

- Community Trust & Research Legacy**
 - Built lasting trust and research infrastructure in Mbale
- For Mothers**
 - Free transport to medical appointments
 - Access to essential medication and care
- For Babies & Families**
 - Personalised long-term follow-up
 - Education on handwashing practices
- For Villages**
 - Infrastructure to support future research
 - Opportunity to contribute to clinical research and healthcare in Sub-Saharan Africa
 - Public randomisation to promote transparency and reduce scepticism

Capacity Building & Knowledge Legacy

- Postgraduate Research**
 - 3 PhDs & 3 Master's students in Uganda
 - Sparked local leadership in clinical research
 - Research areas included:
 - Neonatal omphalitis
 - Congenital Cytomegalovirus
 - Health inequalities
 - Stillbirth causes in Eastern Uganda
- Training & Development**
 - Research nurses upskilled in advanced clinical care
 - Data managers trained in REDCap & statistical tools
 - Community-driven priority setting partnership
 - Ongoing stakeholder engagement & oversight

Trial Staff: Growth, Skills, & Resilience

- Employment & Collaboration**
 - Hired ~100 professionals across 12 disciplines
 - Showcased strong, multidisciplinary teamwork
- Skills & Training Growth**
 - Staff gained hands-on experience in:
 - Protocol writing & study documentation
 - Communication & presentation
 - Clinical research methods
 - Leadership via 3 regional hubs
- Resilience Through Partnership**
 - Tackled COVID-19 disruptions through close coordination with funders, sponsors & stakeholders
 - Held annual multi-site meetings to maintain momentum & unity