PAEDIATRIC ACTIVE ENHANCED DISEASE SURVEILLANCE
(PAEDS)
Study Protocol - Intussusception

BACKGROUND

Intussusception is the most common cause of bowel obstruction in infants and young children with a peak incidence at 4 to 10 months of age [1]. It occurs when one segment of the bowel becomes enfolded within another segment. If this obstruction is not relieved, the vascular supply to the bowel becomes compromised resulting in bowel ischaemia and death. The symptoms and signs in children presenting with intussusception reflect this underlying pathophysiology. Intestinal obstruction results in vomiting, abdominal distension and abnormal or absent bowel sounds. The intussusception and associated oedema may be identified as a mass on abdominal examination. Obstruction to the venous return or arterial supply of the intestine may result in rectal bleeding or the classic "red current jelly" stool. Occasionally patients present in shock due to severe vascular compromise of the intestine, and, if untreated, intussusception may be fatal [1]. The diagnosis of intussusception is confirmed by radiological studies or by surgery. Intussusception is treated by air or hydrostatic reduction enema under x-ray or ultrasound guidance, or by surgery. About 10% of patients require an intestinal resection due to vascular injury to the intestine [2].

Rotavirus infection is the leading cause of severe dehydrating gastroenteritis responsible for >500,000 deaths per year in children <5 years of age worldwide [2]. The development of a rotavirus vaccine for the children of the developing world is an important component of the UN Millennium Development Goals. There was great optimism when the first oral rotavirus vaccine was licensed in the U.S. (Rotashield®, Wyeth). The vaccine was highly efficacious for the prevention of severe diarrhoea and hospitalisation due to rotavirus infection [3-5]. However, Rotashield® was withdrawn 9 months after introduction due to an uncommon association with intussusception [6-8]. This was a major setback in efforts to reduce the global burden of rotavirus disease. Although the risk of development of intussusception associated with receipt of Rotashield® vaccine is estimated to be <1 in 12,000 vaccine recipients it has had important implications for clinical trials of other rotavirus vaccine candidates. Alternate rotavirus vaccines (Rotarix®, GSK and Rotateq®, Merck) have been shown to be safe and effective in clinical trials of >65,000 infants however their safety and performance outside the clinical trial setting in a range of potential clinical or epidemiological scenarios has not been demonstrated [9,10]. Therefore, post-marketing (or post-licensure) surveillance will be an important tool for the detection of rare or unexpected vaccine related adverse events. Both the Rotarix® and Rotateq® rotavirus vaccines have recently been made available for the immunisation of infants in Australia with Rotarix accepted into the Northern Territory's routine immunisation schedule. Universal immunisation against rotavirus is currently being discussed with WHO and other relevant bodies. As these vaccines are introduced it is important to monitor for intussusception to establish if there is any temporal association with receipt of a rotavirus vaccine and intussusception in Australian children. Investigation of possible risk factors for intussusception may provide an insight to the aetiology of intussusception in unvaccinated and vaccinated infants.

STUDY OBJECTIVES

1. To document the incidence of acute intussusception in infants less than 24 months of age
2. To document if a change in incidence of intussusception in infants less than 24 months of age occurs following the introduction of new rotavirus vaccines.
3. To establish if there is a temporal relationship between the development of intussusception and receipt of a rotavirus vaccine or other vaccines

CASE DEFINITION AND REPORTING INSTRUCTIONS

Data on all cases of acute intussusception should be recorded if the following criteria are met:

i. The age is less than 24 months at the time of diagnosis of IS (patient becomes ineligible on the day of their second birthday).

AND

ii. The diagnosis of intussusception is confirmed on air/liquid contrast enema or surgery (based on Level 1 of Diagnostic Certainty using the Brighton Collaboration clinical case definition)[11]

AND

iii. The subject is diagnosed with intussusception during the defined surveillance period

Cases of intussusception confirmed on air/liquid contrast enema or x-ray and resolve spontaneously and therefore do not require air or hydrostatic reduction enema or surgery should be recorded as a case.

All case will require a PAEDS questionnaire to be completed and a stool sample collected. The first stool post reduction is to be collected within 24 hours of the procedure, alternatively the catheter tip from the reduction can be utilised. The specimen should be collected in a sterile container and can be stored in a refrigerator for up to 24 hours. If stored for more than 24 hours the specimen will require freezing. Due to previous studies identifying 40% of IS cases positive for adenovirus in their stool [12], the stool sample (approximately one teaspoon) is to be sent your hospital's laboratory and tested for adenovirus and rotavirus. Centres with an association with the National Rotavirus Centre in Melbourne can send their specimens to Dr Carl Kirkwood care of the Centre.

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