A Comparison of the Effect of Intermittent and Continuous Infusion of Meropenem on the Prevalence of Nausea in Pediatric Cystic Fibrosis Patients

Marissa Cushing  
*Cedarville University*, mcushing@cedarville.edu

Juanita A. Draime  
*Cedarville University*, juanitaadraime@cedarville.edu

Bao-Ngoc Ho  
*Cedarville University*, blho@cedarville.edu

Jordan Nicholls  
*Cedarville University*, jnicholls@cedarville.edu

Bethany Sibbitt  
*Cedarville University*, bsibbitt@cedarville.edu

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Authors
Marissa Cushing, Juanita A. Draime, Bao-Ngoc Ho, Jordan Nicholls, Bethany Sibbitt, Rebecca Widder, Rebecca J. Gryka, and Denise S. Simpson
A comparison of the effect of intermittent and continuous infusion of meropenem on the prevalence of nausea in pediatric cystic fibrosis patients
Marissa Cushing, Juanita Draime, Bao-Ngoc Ho, Jordan Nicholls, Bethany Sibbitt, Rebecca Widder
Drs. Rebecca Gryka and Denise Simpson
Dayton Children’s Hospital

STATEMENT OF THE PROBLEM

• Background
  • Cystic Fibrosis and Treatment
    • Cystic Fibrosis (CF) is a genetic disease, leading to changes of membrane
      secretions causing obstruction of smaller airways
    • CF patients often develop pulmonary infections and require antibiotic
      treatment
    • Loss of lung function increases the risk of death in CF patients
    • Standard treatment involves beta-lactam antibiotics ex. meropenem
  • Pharmacokinetics and Pharmacodynamics of Meropenem
    • Meropenem is a broad spectrum beta lactam that acts by lysing microbes
      through interfering with bacterial cell wall synthesis.
    • Safe and effective treatment, however data on pediatric patients is limited
    • Effectiveness of meropenem determined by time sensitive dosing and is
      effective only when the minimum inhibitory concentration (MIC) is reached
    • Meropenem can be administered as a continuous infusion or intermittent bolus
  • Significance of the Problem
    • There is a lack of information regarding the use of meropenem in pediatric CF
      patients
    • There is a lack of supporting information for the use of one treatment regimen
      over the other
    • Quality of Life – CF patients struggle with malnutrition and treatment with
      meropenem compounds the problem due to significant nausea
    • Would a different dosing regimen reduce side effects of meropenem treatment?

OBJECTIVES

To test establish clinical protocols for meropenem administration in pediatric CF
patients admitted to Dayton Children’s with the goal of reducing nausea as a side
effect.
To assess reported nausea and its relationship to serum concentration of
meropenem in pediatric CF patients after administration of meropenem in either a
continuous or intermittent IV infusion.

HYPOTHESES

Null Hypotheses:
• Continuous IV administration of meropenem will have no effect on the
  side effects of nausea when compared to intermittent administration.
• The differences in serum concentrations between intermittent and continuous IV
  administration of meropenem do not change the number of dosages of anti-nausea
  medications ordered in pediatric CF patients

Alternative hypotheses:
• Continuous IV administration of meropenem will reduce the side effects of
  nausea when compared to intermittent administration
• The differences in serum concentration between intermittent and continuous IV
  administration of meropenem do change the number of dosages of anti-nausea
  medications ordered in pediatric CF patients

REFERENCES

PROPOSED METHODS

Study Design
Crossover study designed to compare blood levels of meropenem and effect on
nausea in pediatric cystic fibrosis patients
Sample
This pilot study will comprise approximately 10 subjects from ages seven to
twenty-one
Data Collection and Measurement
Cross over study
• Patients randomly divided into two treatment groups
  • One initially receives intermittent dosing of meropenem
  • One receives continuous infusion of meropenem
  • Then groups will switch after four days
  • Continuous dose 120 mg/kg/day
  • Intermittent dose 40 mg/kg/dose infused over 30 minutes every 8 hours
Serum Meropenem
• Determined through blood draw
  • Intermittent dose: After the third dose
  • Continuous dose: After day three
Nausea Scale
• Levels of nausea will be determined by recording frequency of Kytril doses
  requested
PICC line
• Levels of nausea will be determined by recording frequency of Kytril doses
  requested
• Sub-study to be conducted to determine reliability of serum levels taken from
  PICC line
  • Serum levels of meropenem in both groups compared between PICC line
    blood draws and peripheral blood draws.
HPLC Assay
• Meropenem concentrations will be measured utilizing a High Pressure Liquid
  Chromatography (HPLC) instrument

PROPOSED ANALYSES

Nausea levels: average the doses of Kytril requested by each patient, number of
episodes of emesis
Two tailed t test (α =0.05, and β = 0.2)
Comparison of the means of two treatment arms.
Concentration of meropenem in blood
Arithmetic mean will be calculated for each sample (95% confidence interval)
Comparison of Treatment Arms
Two-tailed t-test will be used to compare means of the two treatment arms
Two-tailed t-test will be used to compare the two types of blood draw methods

LIMITATIONS

• Small sample size will limit the generalizability of the results.
• Additional medication regimens may contribute to nausea.

FUTURE DIRECTION
The goal of this study is to provide a framework for further multi-site studies of
the same nature.

TIMELINE
September 2013: Obtain IRB approval
September 2013-2014: Enrollment and sample collection
September 2013-March 2015: Sample and Data analysis

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