Lung deposition and systemic availability of fluticasone diskus and budesonide turbuhaler in children
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Study Type: DOE (disease-oriented, not patient-oriented)
Purpose: Assess the lung deposition, absolute systemic availability and basic pharmacokinetic parameters od budesonide and fluticasone in their respective dry powder devices in children with asthma.
Study Duration: each patient inhaled the regimens below, separated by a minimum of 6 days
Trial Design: Pharmacokinetic study
Drugs:
Regimen 1: budesonide turbuhaler 800 mcg (four inhalations of 200 mcg device)
Regimen 2: fluticasone diskus 750 mcg (three inhalations of 250 mcg)
Regimen 3: IV infusion of 200 mcg budesonide (see article for infusion formula and administration technique)
Regimen 4: IV infusion of 200 mcg fluticasone (see article for infusion formula and administration technique)
Protocol:
A. patients received one of the above regimens in a random order, crossover fashion (everyone got each regimen on different study days)
B. the next regimen was used after a minimum of 6 days
C. all patients inhaled both regimens 1 and 2 in random order on the last study day
D. all asthma drugs were discontinued 2 days prior to taking one of the regimens
E. inhalation technique was ensured with pneumotachygraphy

GI absorption from the oropharynx of the drug was inhibited by administration of a charcoal slurry on each study day that a regimen was delivered. They also gargled with mouthwash and water after each inhalation.

Patients: n = 15 children (9 males, 6 females), mean weight = 42 kg, height = 153 cm or 60 inches (5 feet)
Inclusion: children with asthma, FEV1 = > 80% predicted
Exclusion: none mentioned
Outcomes: AUC (area under the curve), Cmax (max concentration after inhalation), T max (time when Cmax occurred), F (absolute bioavailability), MAT (mean absorption time)

1. Are the results valid? not a clinical study, no assessment criteria for pharmacokinetic study

2. What were the results?
* all patients finished the trial
* no statistical difference between the three inhalation study days for FEV1, mean peak inspiratory flow rate, mean inhalation volume,
* similar AUC’s for both drugs
* half-life was twice as long for fluticasone
* volume of distribution was twice as high for budesonide
* peak plasma concentrations were markedly higher and occurred faster for budesonide due to a faster absorption of the drug in the bloodstream (mean absorption time = 5.5 hrs)
* systemic absorption was 4 times higher in the turbuhaler (budesonide) than the diskus (fluticasone) form

Adverse Effects - no assessment

3. Will the results help me?
* Turbuhaler was found to deliver almost four times as much drug to the lungs than the diskus.
* Fluticasone had a slower absorption, a higher volume of distribution and a longer half-life than budesonide.
Conclusion: Research-oriented trial and not clinically based. Article quote: “The results of the present study cannot be used to make conclusions about comparisons of the clinical or systemic effects of the two drug-inhaler devices.” There is no reason to think from this article that one product is more efficacious and safe than the other in pediatric cases, therefore, the clinical utility of this article is poor. This article is best used for the researcher who is designing a head-to-head comparison of the two agents or devices. No practice change should be adopted from the article.