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achieve a good coverage of screening for thalassemic carrier state.

Free Paper Session 8 – Pharmacology

OP054

Effectiveness of salbutamol tablets versus salbutamol aerosol inhaler with spacer in the treatment of acute asthma exacerbation in children: a pragmatic randomized controlled trial

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Introduction

In many developing countries salbutamol tablets are widely used as symptom relievers in childhood asthma. It is no longer listed in WHO Model Essential Medicines List.

Objectives

Aim of this study was to compare effectiveness of salbutamol tablets with salbutamol aerosol inhaler plus spacer as symptom relievers in mild-moderate acute asthma exacerbation in 5-12 year old children.

Method

Balanced randomized single blind two arm parallel group pragmatic clinical trial. Children aged 5-12 years clinically diagnosed with mild-moderate acute asthma exacerbation were randomly assigned to age appropriate doses of salbutamol tablets or aerosol inhaler plus spacer. Primary outcome showed that proportion of children completely recovered in ≤ 3 days. Severity of asthma was measured using Pulmonary Index. Secondary outcomes were mean doses given, duration for complete recovery, side-effects, fast return to school, and recurrence.

Results

Forty-one were assigned to tablets and 44 to inhaler groups. No significant difference observed in mean age, gender and severity ($p>0.05$) between groups. Thirty-five (85.4%) in tablet s group and 40 (91%) in inhaler plus spacer group completely recovered in ≤ 3 days ($p = 0.14$). Both groups were similar for mean doses given [6.51±1.9 vs. 6.25±1.9 ($p=0.72$)], mean duration for complete recovery [2.4±0.55 vs. 2.28±0.55 ($p=0.83$)], fast return to school [91.4% vs.97.5% ($p=0.24$]) and recurrence [17.1% vs. 10 ($p=0.36$)]. Neither groups had notable side-effects.

Conclusions

Effectiveness measured by clinically useful outcomes showed that as a symptom reliever salbutamol tablets are as effective as aerosol inhaler plus spacer in treating mild-moderate acute asthma exacerbation in 5-12 year olds.

OP055

Accuracy and availability of key information in package inserts of medicines used in Sri Lanka

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Introduction

Package inserts (PIs) provide information about medicines to health professionals. Incomplete or inaccurate information may lead to medication errors.

Objectives

Aim of the study was to assess the accuracy and availability of key information in PIs of medicines used in Sri Lanka.

Method

Two samples of 100 PIs each were used to assess availability and accuracy of information respectively. PIs were randomly selected from a government hospital and a private pharmacy. Availability of essential information was checked against criteria specified in the regulations of the Cosmetics, Devices and Drugs (CDDA) Act No. 27 of 1980.Clinical facts in PIs were matched against the British National Formulary and/or Australian Medicines Handbook for accuracy. PIs were categorized as 'compatible' when information was identical, 'partially compatible' if there was at least one mismatch, and 'not compatible' if completely unmatched against references.

Results

Nine types of clinical information (Indication/s, contraindications, precautions, adverse effects, drug interactions, average dose, dose regimen for adult/child, dosing interval and average duration of treatment) were matched with the reference in 100 PIs, resulting in 900 cross-matches. Among them, 61 incompatibilities and 179 partial compatibilities were identified. Contraindications (16%) and precautions (11%) had the highest percentage of incompatibilities. 82% of PIs had at least one deviation from the CDDA regulations. The most frequently missing information was pharmacokinetic data, duration of treatment, overdose, and dosage information in special situations.

Conclusions

Information provided in PIs is inadequate and not completely accurate. Regulatory authorities need to urgently and continuously review PIs prepared by drug manufacturers.

OP056

Metformin: use as a pharmacological agent in management of childhood obesity

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Introduction

Childhood obesity-related metabolic derangements are increasing among South Asian populations. Dietary and physical activity plans have limited effect.

Objectives

This study aims to assess effectiveness of metformin against placebo in management of childhood obesity among 8-16 year-old children in Gampaha District.

Method

A triple-blinded control trial was conducted in a sample of 150 obese school children. After 12-hour overnight fast, blood was drawn for fasting blood glucose (FBS) and lipid profile. 2-hour OGTT was done. Anthropometry, fat mass (FM) and blood pressure were measured. Children randomly received either age-adjusted dose of metformin or placebo, with advice on diet and physical activity. Anthropometry and blood investigations were repeated at 6 and 12 months. Mean difference in outcome measures, adjusted for baseline values were compared between the two groups using ANOVA

Results

There were 84/150 boys and 25 (16.7%) had metabolic syndrome. A statistically significant adjusted mean reduction was observed in metformin group compared to placebo, in weight (-0.991 vs 1.394, p=0.000), BMI-SDS (-0.287 vs -0.116, p=0.000), percentage FM-SDS (-0.092 vs 0.016, p=0.04), systolic BP (-0.415 vs 0.015, p=0.015), total cholesterol (-36.48 vs -27.32, p=0.001), LDL (-26.06 vs -17.22,