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BALANCING SELECTION OFHLA CLASS II AMONG INDONESIANS
(Joeiwono Soeroko)

THE INFLUENCE OF EXTREMELY LOW FREQUENCY (ELF) MAGNETIC FIELDS INDUCTION
TO THE PRODUCTION OF IFN-γ ON BALB/C MICE
(Sudarti, Syarifuddin Mahmud syah, Nuni ha Wahyoo Cahyana)

COMPARISON OF SERUM ESTROGEN AND PLASMA TRANSFORMING GROWTH FACTOR BETA-1
(TGF-β-1) LEVELS IN BENIGN PROSTATIC HYPERPLASIA (BPH) - NON BPH PATIENTS
OVER 50 YEARS OLD AND YOUNGER (30-40 YEARS OLD)
(Soetojo)

ROLE OF MOUTHPIECE ON THE EFFICACY AND SAFETY OF BUDESONIDE TURBUHALER
IN THE TREATMENT OF ASTHMATIC CHILDREN: LESSON FROM M3 STUDY
(Aryanto Harsoro)

THE EFFECT OF KEGEL ON MANAGEMENT OF URINE ELIMINATION PROBLEMS FOR ELDERLY
A Queasy-Experimental Study
(Nursalam, Joni Haryanto, I Ketut Dira)

PREVALENCE OF CATARACT IN DIABETIC PATIENTS AT OPHTHALMOLOGY OUTPATIENT CLINIC,
DR SOETOMO HOSPITAL, SURABAYA
(Sjamsu Budiono)

THE EFFECTS OF ORCHIDECTOMY AND DETORSION AFTER UNILATERAL TESTICULAR TORSION
UPON IMMUNE RESPONSE IN THE CONTRALATERAL TESTIS
(Orangkohardjo E, Hendjowjoto S, Soetojo)

FECAL MATERIAL IN APPENDECEAL LUMEN: ACUTE OR CHRONIC INFLAMMATION?
( IB Pratowo)

THE DIFFERENCE OF THE QUALITY OF LIFE IN THE END STATE RENAL DISEASE PATIENT
BETWEEN CONTINUOUS AMBULATORY PERITONEAL DIALYSIS AND HAEMODIALYSIS THERAPY
(Prawits Priyadi Widoyo, AY Hendiyono)

OCULAR COMPLICATION OF ETHAMBUTOL USED FOR PULMONARY TUBERCULOSIS THERAPY
IN BALAT PENGOBATAN DAN PEMBERANTASAN PENYAKIT PARÚ, SURABAYA
(Sjamsu Budiono)

Review Article and Clinical Experience:
BRIDGING THE GAP IN THE LIPID MANAGEMENT: THE ROLES OF HDL-C IN THE CVES
AND CREATING A NEW CONCEPTS FOR ITS RAISING
(Askandar Tjokroprawiro)

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<table>
<thead>
<tr>
<th>No.</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Balancing Selection of HLA Class II Among Indonesians</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>The Influence of Extremely Low Frequency (ELF) Magnetic Fields Induction to The Production of IFN-γ On Balb/C Mice</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Comparison of Serum Estrogen and Plasma Transforming Growth Factor β-1 (TGF β-1) Levels in Benign Prostatic Hyperplasia (BPH)Non BPH Patients Over 50 Years Old and Younger (30-40 Years Old)</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Role of Mouthpiece on The Efficacy and Safety of Budesonide Turbuhaler in The Treatment of Asthmatic Children: Lesson from M3 Study</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>The Effect of Kegel on Management of Urine Elimination Problems for Elderly A QuasyExperimental Study</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>Prevalence of Cataract in Diabetic Patients at Ophthalmology Outpatient Clinic, Dr Soetomo Hospital, Surabaya</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>The Effects of Orchidectomy and Detorsion After Unilateral Testicular Torsion Upon Immune Response in The Contralateral Testis</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>Fecal Material (FM) in Appendiceal Lumen: Acute or Chronic Inflammation?</td>
<td>-</td>
</tr>
<tr>
<td>9</td>
<td>The Difference of The Quality of Life in The End State Renal Disease Patient Between Continuous Ambulatory Peritoneal Dialysisis and Haemodialysis Therapy</td>
<td>-</td>
</tr>
<tr>
<td>10</td>
<td>Ocular Complication of Ethambutol Used for Pulmonary Tuberculosis Therapy in Balai Pengobatan dan Pemberantasasen Penyakit Paru, Surabaya</td>
<td>-</td>
</tr>
<tr>
<td>11</td>
<td>Review Article and Clinical Experience: BRIDGING THE GAP IN THE LIPID MANAGEMENT: THE ROLES OF HDL-C IN THE CVES AND CREATING A NEW CONCEPTS FOR ITS RAISING</td>
<td>-</td>
</tr>
</tbody>
</table>
Role of Mouthpiece on The Efficacy and Safety of Budesonide Turbuhaler in The Treatment of Asthmatic Children: Lesson from M3 Study

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Abstract

The currently used M0 budesonide turbuhaler mouthpiece is effective and safe. The new M3 turbuhaler mouthpiece is established and expected to be as effective as M0 with lower dose of budesonide. The primary objective of the study is to compare the efficacy and safety of budesonide delivered by Pulmicort Turbuhaler M0 to that delivered by Pulmicort Turbuhaler M3 in asthmatic children, 6-17 years of age. The study start with a 14 day run-in period during which all subjects will inhale a daily dose of 200 μg from Pulmicort Turbuhaler M0 each morning and be randomized to a 12-week treatment period, to either inhale a daily dose of 720 or 180 μg from Pulmicort Turbuhaler M3, or 800 or 200 μg from Pulmicort Turbuhaler M0. Each centre has up to a 6-month period in which to randomize approximately eight subjects. Approximately 48 children will be randomized into each of the four treatment arms. Approximately 24 children from each of the two high doses, bid treatment arms will, at the time of randomization, are enrolled into each of two subset arms. The primary outcome is pulmonary function test results and adverse event. Analysis of the primary efficacy variable of change from baseline to the subject’s % predicted FEV1 during the 12-week treatment period provided results indicating superiority of budesonide turbuhaler over placebo for each formulation (M3 or M0) and each dose, comparability between budesonide turbuhaler M3 360 mg bid and budesonide turbuhaler 400 μg bid, comparability between budesonide turbuhaler M3 180 mg qd and budesonide turbuhaler M0 200 μg qd. Investigation of subgroups and sub-populations for the primary variables of change from baseline to the subject’s % predicted FEV1 during the 12-week treatment period indicated that treatment group differences were similar for the 6-11 year old age groups and the 12-17 year old treatment group, as evidenced by a non significant (p=0.80) treatment by-age-group interaction term. The most frequently occurring AEs in subjects in the safety analysis set during the randomized treatment period were headache (7.8%), nasopharyngitis (7.8%), pharyngolaryngeal pain (6.2%), pyrexia (5.2%), upper respiratory tract infection (5.0%), and cough (4.8%). The incidence of each of these events was generally similar across the treatment groups. In conclusion, lower dose Budesonide with mouthpiece M3 turbuhaler, which is considered more convenient for children, is as effective and safe as M0 with higher dose in the treatment of asthmatic children and adolescents.

Keyword: Asthmatic, children, budesonide, M0, M3, efficacy, safety,

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