G582

PHASE 3 RANDOMISED CONTROLLED TRIAL OF VITAMIN D SUPPLEMENTATION IN 8,851 MONGOLIAN SCHOOLCHILDREN

^{1,2}D Ganmaa, ²G Gantsetseg, ²D Khulan, ²S Ariunzaya, ²B Delgerhe, ²E Sumiya, ²B Amarsaikhan, ³AR Martineau. ¹Harvard T.H. Chan School of Public Health, Harvard University, Boston, USA; ²Mongolian Health Initiative, Mongolian National University of Medical Sciences, Ulaanbaatar, Mongolia; ³Barts and The London School of Medicine and Dentistry, QMUL, London, UK

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Aims To determine the effects of vitamin D supplementation on diverse health outcomes in vitamin D-deficient schoolchildren.

Methods We performed a phase 3 randomised placebo-controlled clinical trial in Ulaanbaatar, Mongolia, to determine whether weekly oral supplementation with 14,000 IU vitamin D₃, administered for 3 years, reduced acquisition of tuberculosis infection in 8,851 schoolchildren aged 6 to 13 years (primary outcome). Secondary efficacy outcomes evaluated in all study participants included incidence of active tuberculosis, acute respiratory infections, atopic diseases and fractures, and growth and muscle strength. Sub-studies evaluated effects of the intervention on bone mineral density, spirometry and pubertal development (n=1,465), physical fitness (n=615) and examination performance (n=2,097). Safety outcomes included mortality and incidence of serious adverse events. Sub-group analyses were conducted for all efficacy outcomes to determine whether the effect of the intervention varied according to baseline 25-hydroxyvitamin D levels.

Results Of the 8,851 randomized participants, 95.6% had vitamin D deficiency (25[OH]D <20 ng/mL) at baseline, and 91.7% completed the study. Mean end-study 25(OH)D levels were 29.8 vs. 9.7 ng/mL in children randomized to intervention vs. placebo (p<0.001). Vitamin D supplementation did not influence the risk of QuantiFERON-TB Gold conversion (P=0.42), incident active tuberculosis (P=0.63), incident asthma (P=0.32), incident atopic dermatitis (P=0.39), incident allergic rhinitis (P=0.45), proportion of children experiencing one or more fractures (P=0.65), mean height-for-age z-score (0.84), mean grip strength (P=0.77), mean bone mineral density at the radius (P=0.14), mean Tanner scores for pubertal development (P≥0.28), mean forced expiratory volume in 1 second (FEV1, P=0.35), mean forced vital capacity (FVC, P=0.95), mean maximal oxygen consumption during a 20 metre shuttle run (VO2max, P=0.22) or mean end-of-year mathematics exam scores (P=0.57). Effects of the intervention did not differ according to baseline 25-hydroxyvitamin D levels (<10 ng/mL vs. ≥10 ng/mL) for any efficacy outcome studied. Neither mortality nor incidence of serious adverse events differed between study arms.

Conclusions A weekly oral dose of 14,000 IU vitamin D₃, administered for 3 years, was safe and effective in elevating 25-hydroxyvitamin D levels into the high physiological range in vitamin D-deficient schoolchildren, but it did not impact any efficacy outcome investigated.

G583

SPARE PENS IN SCHOOLS: A SURVEY AUDITING THE UPTAKE OF THE SPARE PENS IN SCHOOL SCHEME IN PETERBOROUGH

AC Barker, E Wawrzukowicz. Paediatrics, Peterborough City Hospital, North West Anglia Trust, Peterborough, UK

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Introduction Anaphylaxis is a severe and often sudden allergic reaction which can be fatal. Up to 8% of children in the UK have a food allergy and on average most school classes will have 1 or 2 children per class with allergies. In the UK 17% of fatal allergic reactions happened in school which is the driving force behind the spare pens in schools scheme. On the 1st October 2017 the human medicines (amendment) regulations 2017, allowed schools to obtain without a prescription 'spare' adrenaline auto injector (AAI) devices, for use in emergencies. The audit objective was to gauge the uptake of the spare pens in school scheme and to identify potential barriers obstructing uptake.

Method We designed a survey and sent it to 74 schools in Peterborough. We had replies from 11 schools (14%) capturing a total of 6231 students.

Results 5 (45%) schools had heard of the spare pens in school scheme, however only 2 (18%) schools had utilised it. All schools stated they were able to treat anaphylaxis with an AAI device either immediately or within minutes and 5 of the schools (45%) all staff were trained to use AAI devices. We were pleased to hear that 90% of the respondents had allergy action plans in place.

Conclusions The most common reason cited for not utilising the spare pens in schools scheme was the cost of the pens. Pharmacies charge for the cost of the AAI device and may add a handling charge. Unfortunately, at present there are no funds available to help schools cover this cost. As a direct consequence of this audit we are currently in talks with the pharmacy lead for CCG regarding the possibility of mobilising funds to help schools buy spare pens. Our specialist allergy nurse will encourage spare pens uptake at an annual training event planned with school nurses. We will re-audit next year to hopefully demonstrate an improved uptake. We are aware that the audit generated a small sample size and may be subject to bias as the schools who replied could represent the most engaged and up to date schools in Peterborough.

G584

AN AUDIT OF THE EMERGENCY MANAGEMENT OF ANAPHYLAXIS IN CHILDREN IN SECONDARY CARE

A Stratford, V Sharma, A Ali, L Ventilacion. Paediatrics, Lister Hospital, Stevenage, UK

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Aim/Objective There is an increasing incidence in anaphylaxis reported globally and in the UK. Due to this, there is raised anxiety in our local population around the management of anaphylaxis, especially in light of the shortage of adrenaline auto-injector pens last year.

The aim of this audit project is to assess the management of paediatric patients presenting with anaphylaxis to the Paediatrics Emergency Department (PED) and Children's assessment Unit (CAU) and whether they are appropriately managed in accordance with current NICE and local guidelines.

Methods We reviewed the notes of patients who present to PED and CAU from June 2018 until January 2019. Patients were identified through search words such as 'anaphylaxis' and 'allergic reaction' in coding. The notes were reviewed and data collected using the Anaphylaxis Audit Proforma.