MARCH Trial
GP Letter
Version 1.0
Date: 02/11/2005

MARCH Trial

Date:_____

Dear Dr._____,

Re: MARCH Trial-Minimal Access Repair of Contralateral Hernia Laparoscopic versus Open Inguinal Hernia Repair in Infants Multicentre randomised controlled trial

Your Patient,_____, who has a unilateral inguinal hernia has been invited to participate in this multicentre randomised controlled trial.

The aim of this trial is to establish whether laparoscopic repair of unilateral inguinal hernia with closure of a contralateral patent processus vaginalis (PPV) if it is present, prevents the development of metachronous contralateral inguinal hernia in infants.

Despite being the most common paediatric operation performed there is considerable controversy over the best method of unilateral inguinal hernia repair and particularly over the management of the contralateral groin. Infants with unilateral inguinal hernia frequently have a contralateral PPV but the risk of development of metachronous inguinal hernia in these patients is not known. Laparoscopic inguinal hernia repair allows simultaneous diagnosis of a contralateral PPV and its repair. As not all contralateral PPVs will develop into hernias there is currently no evidence that laparoscopic closure at the time of unilateral inguinal hernia repair prevents metachronous contralateral inguinal hernia when compared to open unilateral repair.

The trial is a randomised controlled trial involving surgical units in the UK, Italy and Austria. The trial will compare repair of unilateral inguinal hernia by:

(i) Open technique
(ii) Laparoscopic technique with closure of contralateral PPV

The inclusion criteria for the trial are: infant less than 1 year old with evidence of unilateral inguinal hernia based on medical history and/or clinical examination. The exclusion criteria are: 1)Previous inguinal hernia repair 2)Undescended testis in an infant older than 6 months (since orchidopexy can be safely performed at this age).

The primary endpoint of the study will be development of metachronous contralateral inguinal hernia. The secondary endpoints will be: 1) duration of operation; 2) difficulty of operation; 3) early postoperative complications: wound infection, scrotal haematoma, wound dehiscence; 4) long term complications: hydrocele, acquired undescended testis, testicular atrophy; 5) hernia recurrence rate; 6) testicular volume; 7) cosmesis.

This trial has been discussed with your patient's parents or care givers. The study has ethical approval. Your local paediatric surgery centre will let you know about your patient's progress. Further information can be obtained by contacting the trial coordinator at a.pierro@ich.ucl.ac.uk or by telephone on +44 (0)20 7905 2733.

Yours Sincerely

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