

MIDLANDS

ASTHMA

& ALLERGY

RESEARCH

ASSOCIATION

News

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J A N U A R Y 1 9 9 3

**1992 HAYFEVER
STUDY A
HUGE SUCCESS**

Once again we established a new record for patients entered in to a study of a new treatment for hay fever. Almost 500 volunteers in Derbyshire and Leicestershire (and some from much further afield) helped us to test a new nasal spray: 310 in Leicester and a further 76 in Derby completed the study. We really cannot thank the volunteers enough. Because of our involvement at the leading edge of hay fever research the whole country benefits from their commitment! Many of our volunteers were here for their second, third or even fourth season.

This year's study was an interesting one because we were looking at two separate questions. Firstly, we were looking at two different doses of the treatment to see whether a higher dose is really more effective. Secondly, we were comparing the complete dose once daily in the morning versus administration of half the dose twice daily, in the morning and in the evening.

The last of the data was collected in August. The final amount generated is quite staggering: between 200 and 250 items per patient completing the study, so it takes a long time to process, check and correct before analysis even begins. All being well you will get news of the results in the next newsletter.

**FLIXONASE HAYFEVER
STUDY PRESENTED AT
SCIENTIFIC MEETING**

At the September 1992 meeting of the British Society for Allergy and Clinical Immunology, Dr Stern presented the results of the 1989 hayfever study.

The results showed unequivocally that Flixonase nasal spray is an effective treatment for the relief of runny nose, blocked nose, nasal itching and sneezing. The treatment also helped reduce the number of headaches. Most interesting, however, are some additional results. This was a study to compare morning treatment with evening treatment and we found some evidence that taken in the morning it provides more effective relief than when taken at night. This may well be linked to the timing of peak pollen levels, which tend to be highest in the late morning and early evening. Flixonase has since been approved by the Department of Health and is now available on prescription.

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Clinical Trials

We plan to have a regular article on clinical trials and begin with discussing why we carry out controlled clinical trials at all. In future issues we will cover details of individual trials, the role of the Ethics Committee and the need for "placebo" in clinical trials. If there is something you would like to know about, why don't you write and let us know.

The Need for Controlled Clinical Trials

In 1961 and 62 the "thalidomide scandal" rocked the medical world. The size of the problem was huge. Over 8000 children in 146 countries, about 400 in the UK, were affected after their mothers took thalidomide to relieve anxiety during the early part of their pregnancy.

Why Did It Happen?

Thalidomide was licensed for use on prescription in a very short time after only few animal tests and trials on human subjects loosely designed to see if it worked and that there were no undue problems. Furthermore, because it did not appear to be toxic to rats, it was marketed with such catch-phrases as "completely safe" and "no known toxicity" and there were no contra-indications for its use i.e. doctors were not guided by the

manufacturers to avoid using it for any patient in any circumstances.

In summary, not enough was known about thalidomide, the way it worked and its potential side effects.

Repercussions

In the wake of the disaster, the Dunlop Committee on the Safety of Drugs was set up to investigate and report. Their recommendations led eventually to the Medicines Act of 1968, which was implemented in 1971 and since that time all new medicines and even new ways of using existing medicines, must be approved by the Department of Health. The new system, is now possibly the best in the world.

The Department of Health laid down guidelines detailing what is required for a product licence, and is empowered to inspect company premises. The effect has been greater scrutiny of trial designs to ensure that they are capable of answering the questions posed.

Rigorously defined studies

Very extensive rules have been implemented for the conduct of research on patients especially the monitoring of any unusual effects noticed either by the doctor or patient. No study on humans occurs without all the available data first being reviewed scrupulously by specially set up

and then again by the Government's Medicines Control Agency. The benefit has been more rigorously defined studies producing clearer results. The drawback has been the large increase in the time taken to get a new drug to the market. The average time from discovery to market is now around twelve to fourteen years, rather than the four it took thalidomide.

I suppose there are two sides to every story. Tighter control gives us safer, better understood medicines, but the price we pay is fewer of them, available much later.

Becotide, Bricanyl and Intal, for example, have all come through extensive clinical trials. Likewise, the antihistamines, such as terfenadine (Triludan and Seldane), astemizole (Hismanal and Pollon-eze) and loratidine (Clarityn), and all the others, have successfully cleared the clinical trials hurdle. Clinical trials are difficult, but do give us safer, more effective medicines.

Next Issue

- Behind the Scenes
- Research Project Update

NEW MAARA APPOINTMENT

In April this year, we appointed a Clinical Trials Manager, Dr. Graeme Scott, who joins us from Fisons' UK Marketing Operation. He has a wealth of experience in the pharmaceutical industry, having worked for Boots and more recently Fisons' where he worked as a "Clinical Research Associate" setting up clinical trials for test treatments for asthma and other conditions. He graduated from the University of Bath and went on to Reading University to do his PhD in Statistics.

Role

Graeme's role in the Asthma and Allergy Research Unit at Leicester involves co-ordinating the resources and facilities for conducting clinical trials. In addition, using Graeme's knowledge of the pharmaceutical industry and his extensive contacts we will for the first time be marketing our facilities to attract work

AGM REPORT

At the AGM in May, the Chairman, Richard Keene, reported a happy year for the Association. Due to the co-operation of the Working Party and Executive Committee and the spirit of unity and hard work of the staff, the financial situation which had threatened to close MAARA, has stabilised and the future looks secure. Mr R Blount was elected to the Executive Committee and Mr R Shirley, who resigned, was thanked for his support over the last few years.

Update from Derby

MAARA Derby is now enjoying a busy 1992 and income from the seasonal and perennial rhinitis trials has been very rewarding. Fund-raising income has suffered from the recession and professional competition but income from legacies has been extremely generous enabling us to embark on, and also support, original research once more.

The Aerobiology Laboratory has had its busiest year ever, providing a pollen and spore monitoring service for 12 months of the year. This year it recorded the highest ever oak pollen levels and in June the highest grass pollen counts since 1976. We are pleased to announce that a research paper from this Laboratory 'A Study of Gramineae and Urticaceae in the Derby Area' was published in the journal "Acrobiologia"

The next issue will give a brief summary of the results.

The Treatment Centre continues to provide a valuable service to both private patients and needy patients who are unable to pay. Negotiations with pharmaceutical companies are in progress for clinical trials in 1993 and arrangements are being made with other research organisations for joint projects. The Vernon Street building is undergoing repairs, alterations and improvements, and is beginning to look much smarter.

Newsletter News

We would be happy to help members share ideas in this newsletter. If you have anything the membership would find helpful and informative, please write to MAARA.

From Don Pearson, Vice Chairman

Since our last newsletter there have been quite a number of changes at The Leicester Unit, all intended to be of benefit to patients and the Association. We now have, as you are aware, a Clinical Trials Manager and his ability to generate income for the Association will stand us in good stead as we expand our educational and support services. Without this cash the Association could not expect to flourish.

The Association is planning a series of lectures for members and patients and we hope these will be well supported. The stronger our Association, the more its voice will be listened to.

News l e t t e r

Batting for MAARA



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Residents of Exmoor Avenue, Leicester, got together on Abbey Park in August for a game of rounders organised by Pauline Conway and John Tuddenham. Adults Paid £1.00 each to play and children 50p. After the match they paid for a barbecue and raffled prizes donated by residents and other local of the Anstey Lane club. One enjoyable night's work raised the sum of £102.20 and Dr. Graeme Scott, first left, of the Asthma Research Unit is seen here collecting the cheque.

Recent Donations:

Gratefully acknowledged from:

Leicestershire Branch:
Jalaram Prarthna Mandal
(local Hindu Temple)
Residents of Exmoor Avenue
Leics. Police Committee

Derby branch:
The Crown Inn, Rolleston
John Eastwood Foundation
Sir Arthur Black Trust
The Inner Wheel, Burton
South Stapenhill Club, Derby
Mr. G. Bates
Mrs. P Garrett
Mr. & Mrs. Gilman
Mrs. Blacklock

Sore Throats

Inhaled Steroids can sometimes cause sore throats. It is sensible to rinse your mouth and gargle after taking Becotide, Becloforte or Pulmicort.

Cleaning Large Spacers

Rinse 'Volumatics' and 'Nebuhalers' occasionally. Try using a long-tufted toothbrush to keep the mouthpiece clean by regular brushing.

MAARA Membership

MAARA members have a very important part to play in the Association. At present we have 275 members, and are hoping to increase the membership. If you know of anyone who suffers with asthma or allergies, or just friends who would like to give their support, we would be delighted to hear from them.

How to join MAARA

The annual subscription is £3, and £10 for a five year subscription. Contact either the Derby or the Leicester office (see below).

How to contact us:

The Midlands Asthma and Allergy Research Association (MAARA) is registered as charity No. 257131 under the Charities Act, 1960.

Head Office, 12 Vernon Street, Derby:
Tel.(0332) 362462. The Associations administrator is Mrs Ann Harries.

The Chairman of MAARA is Councillor Richard Keene. He can be contacted through the Head Office. The Vice-Chairman is Mr Donald Pearson, 56 Penzance Avenue, Wigston, Leicester.

The Leicester Branch is the Asthma and Allergy Research Unit, Leicester General Hospital, Gwendolen Road, Leicester, LE5 4PW, Tel.(0533) 735090.