

Goat's Serum

This is what some people are saying about Goat's Serum –

"It's miraculous – I'm 90% better!"

"It's magic – I can walk a couple of miles now."

"Almost immediately, I could walk faster, better, quicker."

"It's nothing short of amazing"

"The great majority – 85% – have a positive response – anything from very small to very huge."

So could this be the Big New Treatment for MS?



When *The Sunday Times* ran a news story in January saying "Goat serum jabs help MS victims to walk again", it lit a fuse. Since then, the scientists, hospital and company mentioned in the article (as well as the MSRC!) have been snowed under with phone calls, letters and e-mails from people with MS desperate to know more and go on the treatment.

Judy Graham, Editor of *New Pathways*, gets the full EXCLUSIVE story.

Q What is Aimspro – the trade name for the Goat's Serum?

A It's the purified serum taken from goats which have been vaccinated against a highly specific immunogen.

A small amount of blood is taken from live goats, who are not killed in the process.

Q How does it work?

A The exact mechanism of action is not totally understood yet. Aimspro is a biotechnology product using polyclonal antibodies (see box on p11). The exact technique cannot be disclosed due to the need for commercial

confidentiality.

The worldwide patent for the product says that the goat produces antibodies against the HLA class 2 part of the immune system. It causes a cascade whereby the immune system is able to cope with the antigen.

Q Does Aimspro Work?

A It is reported to 'work' for 85% of MS patients. This means that they improve, from slightly to dramatically; it may also prevent or delay the progression of the disease. No one knows why it works for some people more than others.

Q How did this treatment come about?

A An American scientist called Stan White identified a new mechanism whereby serum from specially immunised goats could treat several human diseases.

He did not have the money to take this further but was put in touch with British entrepreneur David Shotton, founder of Daval

International, who had the funds to buy the rights to develop the science and the treatment.

Since then, all the laboratory work and development of the product has been done in the UK.

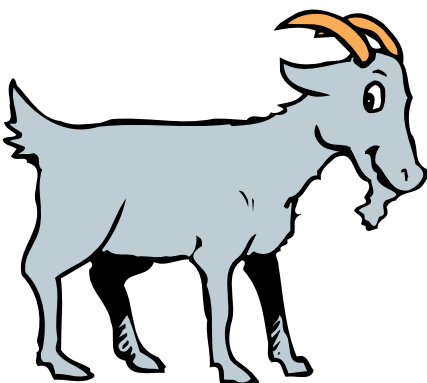
The goats are reared in the USA where the raw product is also prepared. It is then shipped to the UK for purifying.

Q Why Goats?

A Goats are a commonly used animal in biotechnology and medicine. They are large enough to produce ample quantities of product, yet are easily managed in a controlled environment.

Q Where do the Goats come from?

A The pharmaceutical grade goats used in the treatment come from a United States Department of Agriculture licensed research farm in USA but are a breed of goat originally from South Africa. All the goats are very healthy and well



Goat's Serum (continued)

Q Who are Daval International?

A They are a small British research and development company which was started in 2000 by wealthy entrepreneur and venture capitalist David Shotton from south London. He was about to retire when a contact in the US asked if he could put some money in to a new medical treatment derived from goat's serum. He became fascinated by the project and its potential to help ill people and put in £5m of his own money. The company now also has on board a banker,

financiers, doctors, and scientists.

David Shotton says: "When I first got involved, I had no idea what I was getting myself into, or quite how much money would be needed to take a new medicine to market." But he saw how his own niece by marriage had improved on the Aimspro treatment, and was convinced. He says: "I was hooked. It was do or die. I knew I had to do everything I could to get this treatment into the hands of those who desperately need it."

Managing Director Brian Quick says: "We are on a mission. We

don't know whether we can cure people with MS, but we absolutely know that we can improve their quality of life and in the majority of cases enable them to live normal lives."

Of the 700 shareholders, some are happy patients; others are friends and family who want to help.

Being a small company, Daval is willing to investigate ways in which it may team up with a larger pharmaceutical company to market and distribute the product.

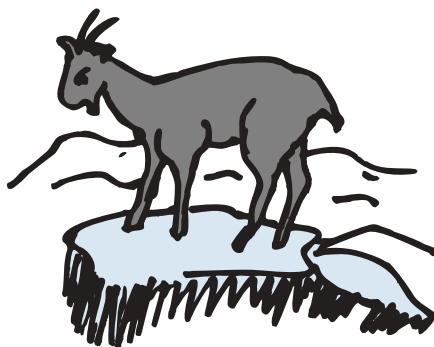
maintained. There are enough goats to supply serum to treat MS patients worldwide, although the process is very expensive at the moment – it will become much cheaper once the treatment is approved and licensed.

Q How is the treatment given?

A By simple injection under the skin – upper arm, thigh, buttock. Patients are taught how to inject themselves, using the same sort of needles as diabetics. The injection is simple, fast and virtually painless.

Q Are there any side effects?

A Hardly any have been experienced by those treated so far, though some people may experience a red patch at the site of injection. All new patients are given a test injection of 0.1ml to make sure there are no adverse reactions.



Q What MS symptoms does it treat?

A All. Treated patients most often mention improvements in walking ability, bladder and bowel problems, strength, balance, fatigue, better control of fine movements, well being, feeling more mentally alert, and more 'normal'.

Q Is Aimspro a cure for MS, or a treatment?

A It's a treatment which has to be given once a week probably for life. If you stop taking it, the MS can get worse again. So it's definitely not a cure.

The Scientist: Professor Angus Dalglish

"It's all about new pathways."

Professor Dalglish, of St George's Hospital in south London, a renowned oncologist, is a key player in the Aimspro story.

How does it work in MS?

Professor Dalglish says: "It's all about new pathways. It inhibits a powerful inflammatory pathway and activates another

pathway of the immune system which is over-active in MS. The product induced in the Aimspro treatment inhibits this pathway, but the beneficial effects go far beyond the pathway explanation."

Now that so many patients have benefited from the treatment, Professor Dalglish feels it should be taken seriously by the medical community. "The vast majority have had subjective improvement, and for

these patients, subjective improvement is very important – such as being able to turn over more easily in bed."

The Aimspro treatment is unique in that it was not tested on animals before being tried on humans. "We by-passed animals as we could not think of an animal model. The particular pathway we were working on is only found in humans. So if we had tried it on animals, it would not have worked."

The GP who gives the treatment: Dr David Maizels

Dr Maizels, a GP from Chislehurst in Kent, has been running an informal trial with around 130 MS patients on an 'informed consent' basis. So he has observed more patients on the goat's serum treatment than any other doctor.

"It works. The great majority – 85% – have a positive response – anything from very small to very huge. Sometimes it works incredibly rapidly – patients get relief within minutes. At times, it is nothing short of amazing.

With MS, something is impairing nerve conduction. There is a hostile environment to nerve conduction. Aimspro reverses this hostile environment and you get return of function."

Time and time again, Dr Maizels has seen MS patients

make startling and dramatic improvements. "I had one woman with MS come in to my surgery in a wheelchair. By the third week of treatment, she was walking through my door on crutches.

"It's more dramatic when they come out of wheelchairs – and 1 in 5 do. The results may be harder to assess in the 'walking wounded', but you often see improvements in more subtle things like strength, muscular tone, staggering gait, response to heat, optic neuritis, and bladder and bowel control.

But what about the 15% who do not have a positive response? Dr Maizels says it is only in about 5% of cases that Aimspro does not work at all. The other 10% may be too severely disabled to benefit, get some psychological advantage from being ill, don't really want to

try, or don't come for treatment because of cost or distance.

What about the placebo response? Couldn't that be the reason it's working for so many MS patients? "Absolutely not," insists Dr Maizels. "I was sceptical about this at first and thought it must be placebo. But from having seen the response, I am sure now that it is not placebo."

Dr Maizels is confident that the trials will show significant results. "I think patients will go up on the disability scale, with a mix of objective and subjective improvements.

I think this will be THE treatment for MS. It works. Nothing has ever caught my imagination like this. Here is a product which exceeds anything else in the market place bar none. There is a huge need out there, and this will help people."

What are Polyclonal Antibodies?

Polyclonal antibodies are proteins produced by white blood cells in response to an antigen (foreign protein). Different antibodies recognise different parts of the antigen, and destroy or neutralise it.

'Aimspro' uses polyclonal

antibodies from the serum (the fluid portion of blood) of goats that have been inoculated with a variety of vaccines to generate neutralising antibodies.

Polyclonal antibodies work better than monoclonal

antibodies. Says Dr David Maizels, "With monoclonal antibodies you only get part of the whole picture – like just seeing your elbow. But with polyclonal antibodies, in terms of getting a response, it's the whole picture."

The Medical Trials Secondary Progressive MS

The main trial into Aimspro for MS is being conducted at The Atkinson Morley Wing of St George's Hospital Medical School in Tooting, South London. The consultant in charge of the trial is Dr David Barnes, a leading neurologist in the field of multiple sclerosis. These clinical trials meet all the stringent scientific criteria – they are double-blind, placebo-controlled and randomised.

The aim of the trial is to see if this drug prevents or delays the progression of MS. It will also be able to see if patients have improved.

Dr Barnes heard about the informed consent treatment of Aimspro, and was sufficiently impressed by the anecdotal results from Dr Maizels to do a proper scientific trial on it.

Some patients have already started on the trial, with more being recruited until the total of 40 is reached.

Success will be measured by seeing how much subjects have gone up on some disability scales.

If there are dramatic results, the trials would have to be stopped early. Says Dr Barnes: "The more effective it is, the quicker it will become available. It would be wonderful for MS if it did work. That's why I took it on."

If 'Aimspro' works for secondary progressive MS, it will almost certainly also be available to patients with relapsing/remitting and primary progressive MS.

Goat's Serum (continued)

Case: Alan Osmond

"Almost immediately, I could walk faster, better, quicker."

Alan Osmond, 54, is the eldest of the Osmond Brothers, the American pop group who became famous in the 1970s. He was diagnosed with MS 17 years ago. A Mormon, he lives with his wife Suzanne and 8 sons near Salt Lake City, US.

When Alan Osmond first heard about the goat's serum treatment, he was sceptical. "I thought, here's just another product." Over the years, he'd been on all kinds of treatments, including Copaxone, but none had really helped so why should this one?

But when Alan saw how much other MS patients had improved on the goat's serum, he thought, why not give it a go? After all, his MS was getting worse, with numbness on his right side, sluggish eyesight, and a rogue bladder and bowels. He



Alan and Suzanne Osmond

could walk one block, slowly, badly, and with a cane.

So Alan came to England and had two weekly injections from Dr Maizels. After the first treatment, he noticed a dramatic improvement. "I noticed right away that I had more strength in my right side. Before the treatment, you could easily have pushed my hand down. But after the treatment, you couldn't.

"Almost immediately, I could walk faster, better, quicker. And

at dinner that night I could cut the steak myself – something I haven't been able to do for around five years. Right away, my bladder improved, and my mind felt fresher."

Over the next 48 hours, he continued to get better. "I went with my wife to a mall and was able to walk all the way round – before I had to get round in one of those electric carts.

"Also, I used to wear a leg brace because of foot drop and my knees used to buckle under me. Now I don't need the leg brace."

Alan's wife Suzanne witnessed the dramatic improvement: "His whole posture changed before my very eyes. Before, he was slumped and lethargic. But after the treatment he became more sturdy, his balance was better, he could see more sharply and think more clearly. It takes the MS symptoms away. Alan is on the road to recovery. We are very blessed."

Q Where can I get the Treatment?

A A GP in Chislehurst, Dr David Maizels, (see box on p 11) has been giving treatment to volunteers on an 'informed consent' basis for the last two and a half years. So far he has treated more than 100 MS

patients, often with "astounding results". These people heard about Dr Maizels through 'friend of a friend' contacts.

Two clinical trials are presently underway to test Aimspro for MS: The largest is at the Atkinson Morley wing of St George's Hospital in south

London for secondary progressive MS. (See 'Trials' box.)

Daval International anticipates a great demand from patients to have the treatment as it becomes more widely publicised. However, they are restricted by the need to ensure the validity of the trials, the fact that the

Case: Billy Edmiston

"It's magic! I can walk a couple of miles now."

Billy Edmiston, 60, from Southsea, Hants, was diagnosed in 1988. He has been having one treatment of goat's serum a week for 16 months.

"Goat's serum is the most amazing thing, with no side effects. I've been improving the whole time I've been taking it.

I'm oodles better than I was before I started.

In the last couple of years my MS was accelerating and I was finding it much more difficult to walk. I couldn't go out without a stick and the most I could manage was 10 steps. Now, I can walk a couple of miles.

Also, my bladder control was getting worse and all my journeys were planned on where the toilets were. It was soul

destroying. Now, my bladder and bowels are absolutely normal; I ignore them.

I saw a difference within the first 20 minutes. When I went to see Dr Maizels the first time I went in with a stick. But I walked out without any help. Afterwards, we went to the pub and I could walk up and down the steps – something I haven't been able to do for ages."

Case: Pauline Johnson

"It's miraculous! I'm 98% better! I am in control of my life again."

Pauline Johnson, 45, from Beckenham in Kent, was diagnosed with MS 6 years ago, although her symptoms go back 17 years. She was the first person ever to be treated with goat's serum and has been on it for 5 years but has kept it quiet until now. "I've wanted to shout about this from the rooftops!" she says.

"I'd got to the point where I had nothing to lose and was a willing guinea pig. I could only walk while holding on to things, my balance had totally gone, my bladder and bowels were absolutely terrible, with incontinence and severe

constipation, I had spasms and I would be lost for words during a conversation. I had become a hermit and didn't want to see anyone.

It's miraculous! Now, I'm 98% better. I can walk a few miles, which is a joy.

For me, the most dramatic result was after the first and second shot. I saw immediate improvements – I could get up easily from a sitting position. My skin colour changed, my appetite improved and I felt and looked better.

It's taken the whole of the five years to improve this far. I saw massive improvements in the first year, then reached a plateau. After that there were subtle changes, like I could pick things up without dropping

them, get out of a chair on my own, my conversation improved. Also, I look better. Before, I was the colour of wallpaper paste. Now I look well.

The goat's serum treatment has helped me no end. It's given me back my confidence and dignity, and given me back to my family. I feel like a proper person again and that I'm in control of my life.

I still have to be careful, though. If I overdo it I get tired and have to rest. There is still a weakness in the bladder and bowels, but it's nothing like it was. It's an ongoing treatment. I don't mind taking it for the rest of my life. I am not 100%, but I am happy to stay the same way I am now. I am the luckiest person in the world."

treatment has not yet been licensed and their own financial inability to treat all those patients who fall outside the trial criteria.

They have already received hundreds of very moving letters asking for advice about how to get on the trials, or if that is not possible, how to get the treatment directly. Brian Quick, Daval's MD says "Although we will do nothing to prejudice the authorised trials we are conscious that we must do everything possible to alleviate the suffering that this dreadful disease is causing."

Q How soon will Aimspro become available?

A If the results are as good as expected, it is still unlikely to be less than 2 to 3 years (which in terms of medical research is fast). The present trials are Phase II/III. If it becomes obvious that the treatment group is doing significantly better than the control group, then it is possible that the trial would be stopped on ethical grounds. However, it would still need to go through a Phase IV trial, involving a large number of patients in several centres.

It normally takes eight years and a hefty £80m for a pharmaceutical product to reach the stage where Aimspro is now.



Info Box

Applications (only from a GP or neurologist!) to join the main trial to be sent to:
Dr David Barnes, Consultant Neurologist,
Atkinson Morley Wing,
St George's Hospital, Blackshaw Road,
Tooting, London, SW17 0QT

Trial Nurses:
Michelle Hollow and Christine Gregory
Tel: 0208 725 4162

Daval International
www.davalinternational.com

Case: Mark Chippendale

Mark Chippendale, 44, from Sevenoaks in Kent, a former chiropractor, was diagnosed with MS 6 years ago. Even though his speech is still slurred and he has many MS symptoms, he still feels that the goat's serum is working for him in important ways.

"I am the worst responding case there is of everyone. Someone's got to be the worst! But I feel I am doing very well. I've been going through the terrible stress of a divorce but have not got worse. If I hadn't been on the goat's serum I think I would be a lot worse. I am more stable standing up and my

walking is a little bit improved but I still need a zimmer frame. My MS is still bad in terms of speech, but on a graph you would see overall improvements. I am a bit envious of the people doing dramatically well on goat's serum, but the important thing for me is that I am not going downhill."