



## ORIGINAL PAPER

# Homeopathic *Secretin* in autism: a clinical pilot study

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**Autism is a condition characterised by impairments of social communication, social interaction and social imagination. The exact aetiology of autism is unknown but some autistic features have been explained by the 'opioid excess theory' in which excess brain peptide levels have a morphine-like activity. Reduction of peptide levels by administration of the duodenal enzyme *Secretin* has been found to improve social and language skills in autistic patients. Homeopathic *Secretin* has been said to produce similar effects. A pilot study was undertaken to study these effects by administration of *Secretin* to a group of autistic patients. Weekly assessment for 12 weeks was performed by the patients' care workers. Statistical analysis of the mean pre-treatment results compared with the mean treatment results suggested a worsening in the autistic symptoms during treatment. Discussion with the care workers revealed changes and some improvements that were not recordable on the scoring system. Further research into *Secretin* treatment of autism using a more detailed and customised scoring system would be justified. Following this pilot study a randomised controlled trial of *Secretin* vs placebo would be appropriate. *British Homeopathic Journal* (2001) 90, 86–91.**

**Keywords:** autism; *Secretin*; outcome study; homeopathy

## Introduction

Autism is a developmental disorder characterised by a 'triad' of impairments in social interaction, social communication and imagination.<sup>1</sup> As a consequence of these impairments people with autism have great difficulties in relating to others, developing friendships or making sense of the world around them. There may be accompanying learning disabilities which compound the difficulties experienced by autistic patients.

Autistic patients can be affected to varying degrees, some severely, others in a milder more subtle form. This range of conditions is known as the autistic spectrum. At the less severe end of this spectrum is a form of autism known as Asperger's Syndrome.<sup>2</sup> These patients have better communication skills and have a desire to form relationships but they lack the

insight into the subtleties of social interaction. They frequently have associated depression.

At the less able end of the spectrum there are extreme difficulties with social relationships, sufferers often appearing aloof and indifferent to others, difficulties with verbal and non-verbal communication with lack of understanding of the meaning of body and facial gestures. There is also poor imagination, with an inability to develop imaginative activities and play, leading to repetitive and rigid behaviour. The diagnosis of autism is made on the history and detailed assessment of the pattern of skills, disabilities and behaviour of the individual patient.<sup>3</sup>

There is no curative treatment for autistic disorders. Psychotropic medication is often used for specific situations such as extreme agitation and restlessness. Management of patients with autism is achieved through environmental and behavioural techniques.<sup>3</sup> Moderate and severely affected patients need intensive supervision, often in the residential setting, where specialist education, care and support can be provided.

The exact aetiology of autism is unknown but thought to be due to genetic factors.<sup>4</sup> Neurobio-

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logical studies of individuals with autism suggest abnormalities at the cellular level.<sup>5</sup> Research has also shown that autism may be associated with a variety of conditions occurring during pregnancy or neonatally. It is also suspected that the gut of autistics may be abnormally permeable, allowing the uptake of long chain molecules<sup>6</sup> such as peptides. The causation of autism has also been explained by the ‘opioid excess theory’.<sup>7</sup> This theory proposes that peptides derived from incomplete digestion of certain foods<sup>8</sup> (in particular casein from milk and dairy produce, and gluten from wheat cereals) have morphine-like activity, which manifest as the symptoms of autism when concentrated in the brain. Serum peptide levels are controlled by the duodenal hormone *Secretin* which has a number of functions including stimulation of the pancreas to secrete the enzyme peptidase. This enzyme’s function is to metabolise peptides in the gut, which in turn lowers the peptide levels both peripherally and in the brain. Thus secretin’s effect of lowering peptide levels in turn reduces the ‘morphine-like’ autistic features attributed to excess peptides.

The use of *Secretin* for treatment of autism followed a serendipitous observation in 1996. An autistic 4-yr-old with gastrointestinal dysfunction was being investigated with a pancreatic stimulation test in which the hormone *Secretin* is administered intravenously. A marked improvement in many of the child’s autistic symptoms followed this test.<sup>9</sup> As a result of this observation, a considerable number of autistic children have been treated with secretin. There have been many anecdotal reports of improvements in social interaction, communication including speech, attention span, compliance, eye contact and sleep habit. These findings have been confirmed in a clinical trial on *Secretin* in autism.<sup>10</sup>

*Secretin* is administered intravenously. Occasionally there is an exacerbation of the autistic features over the first few days but by about 2 weeks improvements are seen which may last 6–8 weeks.<sup>11</sup> At the present time there is no licence for the use of *Secretin* in the treatment of autism. In order to get around the practical problems of intravenous administration and its expense and thus to make it more widely available, homeopathic *Secretin* has been produced by Ainsworth’s Homeopathic Pharmacy. An outcome audit is being performed by Ainsworth’s on autistic children. Parents are asked to complete a checklist of symptoms whilst their child is taking the *Secretin*. There have already been many favourable responses to the medicine, similar to those found in *Secretin* given intravenously.

In order to investigate *Secretin* I set up a pilot study in which 12 autistic patients were treated and assessed over a 12-week period. The objectives of the study were to:

- Record the effects of *Secretin* treatment in autism.

- Statistically quantify the effectiveness of *Secretin* in autism.
- Support or question the claims made of *Secretin*.

If *Secretin* proved to be effective I foresaw the following benefits:

- Improved quality of life of autistic patients through a greater ability to interact and communicate.
- Families and carers would find the autistic patient more manageable, making their care less stressful, tiring and frustrating, thus more rewarding.
- Homeopathic *Secretin* is easier to administer compared to intravenous secretin.
- Expense—homeopathic remedies can be prescribed on the NHS, free of charge to those who are exempt of payment.
- Greater availability of *Secretin* compared to intravenous secretin, thus enabling greater numbers to receive the treatment.

If this pilot study demonstrated a clear improvement of symptoms I would hope to proceed to a full random controlled trial on a larger group of autistic patients to investigate further the effects of *Secretin*. If the study disproved the claims and benefits of *Secretin* I would consider conducting a further pilot study with modifications that had been learnt through the present study. I would consider using a higher potency of *Secretin*. If further studies still demonstrated no change or improvement in autistic symptoms this would be valuable for the cause of autism. Proving a new treatment to be ineffective dispels ‘false hopes’ that patients may have in a so-called ‘miracle cure’.

## Patients and methods

The pilot study was conducted on 12 autistic patients living in residential care. Their ages were between 24 and 43. The patients had varying degrees of severity of autism. They also had widely differing presentations of the autistic spectrum of impairments. See Table 1 for patient details. The diagnosis of autism in each patient was made by a Consultant Psychiatrist specialising in this condition prior to transfer to the residential units.

The patients are under constant supervision by their care workers. They live in either a residential unit housing up to nine patients or in adapted housing in which two patients live in each house. Each patient has a care worker providing continuous individual supervision. During the day the patients attend a ‘Day Care’ centre where they have further supervision with behavioural and educational stimulation. A key feature of care is the maintenance of an extremely well structured regular daily routine, in an environment in which there is as little change as possible. Continuity and consistency of the care workers is also integral to the success of the patients’ management.

The majority of patients are maintained on various combinations of medication prescribed on the

**Table 1** Patient details. Main features of autistic behaviour

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<i>Patient NB</i>
Male, 33 y.
Pre-treatment CARS score 40.75.
Aloof. Apart. Separate. Attention seeking behaviour. Hits out when angry.
<i>Patient NC</i>
Male, 34 y.
Pre-treatment CARS score 32.25.
Aloof. Needs to be occupied/set tasks/to have guidance. Doesn't like interference.
<i>Patient JS</i>
Male, 39 y.
Pre-treatment CARS score 43.
Strict bedtime routine extremely important. Tipping bins up and emptying on ground. Eating insects and cigarette butts off floor.
<i>Patient RP</i>
Male, 23 y.
Pre-treatment CARS score 38.
Bizarre behaviour. Extreme sensitivity to change. Anal/faecal fixation.
<i>Patient IJ</i>
Male, 31 y.
Pre-treatment CARS score 38.
Aggressive. Challenging behaviour. Self-abusive. Anger. Obsessive/compulsive with TV soap operas and trains.
<i>Patient SD</i>
Male, 31 y.
Pre-treatment CARS score 24.5.
Fear of change. Inflexible. Lacking verbal communication. Poor imagination. Poor social interaction and understanding.
<i>Patient GP</i>
Male, 43 y.
Pre-treatment CARS score 27.5.
Aloof. No verbal communication. Fixation with car tax discs. Obsessed with dates.
<i>Patient AK</i>
Male, 43 y.
Pre-treatment CARS score 27.5.
Passive. Echolaic. Cyclical self-harm behaviour. Regurgitation and rumination.
<i>Patient EN</i>
Female, 27 y.
Pre-treatment CARS score 42.25.
Social interactions strange. Constant reassurance sought. Extreme tension and insecurity. Inflexible use of language.
<i>Patient SS</i>
Male, 24 y.
Pre-treatment CARS score 40.75.
Aloof. Violent with stress. Minimal interaction and involvement.
<i>Patient KC</i>
Female, 38 y.
Pre-treatment CARS score 35.75.
Active but odd. Strange thought content. Obsessive. Inflexibility.
<i>Patient ME</i>
Male, 42 y.
Pre-treatment CARS score 45.
Rigid routine. Self-stimulation. Rigid use of language.

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instruction of the local Psychiatrist with a special interest and experience in these conditions. There is regular attendance by the Psychiatrist as well as close liaison with myself and partners as well as their General Practitioners.

Written consent for inclusion into the pilot study was obtained from the parents of the patients. Approval for the study was kindly granted by Wessex Autistic Society. The study was conducted over a 12-week period, during which there was no change in the normal daily routine for the patients. The medication remained unchanged in all the patients except one.

The patients were assessed using a Childhood Autism Rating Scale (CARS).<sup>12</sup> This is an internationally accepted scoring system, in use since 1971.<sup>13</sup> It is a behavioural rating scale designed to be used in children to diagnose autism and quantify their degree of disability. The scale has been successfully dem-

onstrated to be of use in adults.<sup>14</sup> It consists of 15 questions aimed at assessing the triad of symptoms of autism. Each question is scored by giving a rating of 1–4. A rating of 1 indicates that the patients' behaviour is within normal limits; scores 2, 3 and 4 indicate mild, moderate and severe abnormality, respectively. When the rating falls between each of the categories, mid-point readings were given. The total score was then calculated and recorded as the rating on that particular week's assessment. In the pilot study, the care workers completed the CARS checklist once every week during the 12 weeks of treatment with *Secretin*. Ideally each assessment was to be completed by the patient's individual care worker throughout the study to eliminate variation in the carers personal interpretation of the questions. Assessments were also made weekly for 2 weeks pre-treatment. This provided the autism baseline level for the patients.

**Table 2** Weekly autism scores for each individual patient throughout the study

Patient	16 Mar	23 Mar	30 Mar	06 Apr	13 Apr	20 Apr	27 Apr	4 May	11 May	18 May	25 May	01 Jun	08 Jun	15 Jun	22 Jun	Pre-treatment	Treatment mean
NB	47	34.5	32	42	41	45	40.5		42.5		38	48	33		42.5	40.75	40.45
NC	39.5	25	30	40	36	38.5	36.5	32.5	31.5		41.5	35.5	35.5		38.5	32.25	36.00
JS	44	42	37.5	43.5	46	41	47	34	39.5		47	48	39.5		46.5	43.00	42.68
RP	48.5	27.5	53	50.5	36.5	56	42	41.5	45.5		46.5	47.5	44		53.5	38.00	46.95
IJ	43	33	31	40	24.5	42	33.5	33	29.5		33	35	32.5		40.5	38.00	34.05
SD	25	24	33.5	20	16	19.5	25	24.5	16.5		23	27	21		26.5	24.50	22.95
GP	26	29	27	29	41	34	31	27.5	33		33	45	38		30	27.50	33.50
AK	49	48.5	48	53.5	50.5			50	51	53.5		53.5	56	57		48.75	52.56
EN	41.5	43	42	42	40	42		42.5	42	41		42	43	43.5		42.25	42.00
SS	40.5	41	40	40.5	42			41	44.5			41.5	47.5	47	48.5	40.75	44.29
KC	37	34.5	36	41.5	42.5	40.5		41	41	40		41.5	44	43		35.75	41.10
ME	44.5	45.5	49	44	48	43		43.5	42	42		42	41.5	42		45.00	43.70
<b>Mean</b>	<b>40.45833</b>	<b>35.625</b>	<b>38.25</b>	<b>40.54167</b>	<b>38.66667</b>	<b>40.15</b>	<b>36.5</b>	<b>37</b>	<b>38.20833</b>	<b>44.125</b>	<b>37.42857</b>	<b>42.27273</b>	<b>39.625</b>	<b>46.5</b>	<b>40.8125</b>	<b>38.04</b>	<b>40.02</b>

The *Secretin* 6c was produced by Ainsworth's, a registered homeopathic manufacturer. The medicines were prepared following Blackie Foundation Guidelines. It was supplied in liquid form; five drops were added to 5 ml of water and given orally twice daily.

Throughout the study I kept in close contact with the staff of the residential homes, especially during the first 2 weeks of treatment in case any aggravation reactions occurred. The carers were instructed to contact me with any queries. In the unlikely event of an adverse response to the medicine it would be stopped immediately and I was to be contacted for advice. If there was a significant adverse effect at any stage the patients would be withdrawn from the study.

At the close of the study, the test scores were collated and statistically analysed.

## Results

The results are displayed in Table 2. Weekly mean results are seen at the bottom of each column. Pre-treatment and treatment means are given in the last two columns. Comparison of the mean pre-treatment scores with mean scores during treatment show that the mean CARS score increased while on *Secretin* by about 5%. This concludes that the patients' autistic symptoms worsened and they deteriorated during treatment.

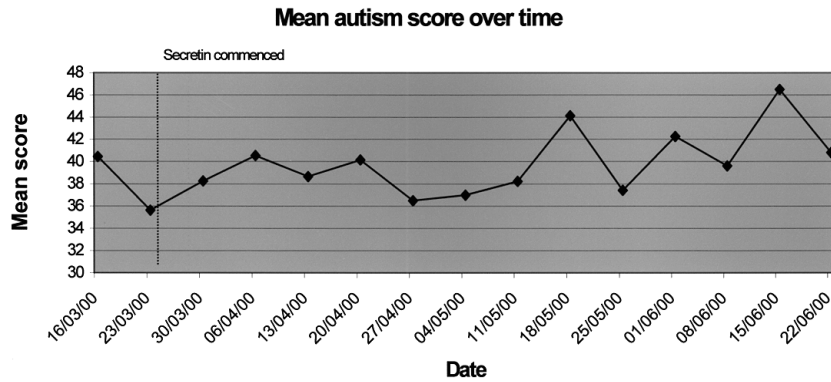
The comparison of the pre-treatment and treatment means using the Wilcoxon Test gave a test statistic of  $Z = -1.18$  and  $P = 0.099$ . As  $P > 0.05$ , it can be concluded that there is no significant change in the CARS score due to treatment.

The weekly mean results are also presented in graphic form (Figure 1). There is a small increase in mean score during treatment. The week to week changes became more variable and pronounced with time as treatment continued.

## Discussion

The results demonstrate that in this pilot study of 12 patients *Secretin* 6c twice daily did not improve the autistic symptoms and behaviour. Mean treatment scores during treatment exceeded the mean pre-treatment scores. These results demonstrate an increase in autistic symptoms and a deterioration in behaviour while taking *Secretin*.

However, the overall statistical analysis did not support the observations made by the care workers of the autistic patients. In 6 of the 12 patients studied, the care workers described improvements in autistic symptoms and behaviour. After the study individual patients were discussed in case conference with the care workers. The following observations illustrate the improvements noted whilst taking *Secretin*.



**Figure 1** Mean autism score over time.

Patient RP normally has frequent outbursts preceded by ‘signing’. While on treatment there were less severe and shorter lasting outbursts with a shorter recovery phase.

Patient NB who normally communicates by varied vocal noises made more sounds and was certainly louder.

Patient JS was more communicative, vocal and demanding while taking *Secretin*. He was more cooperative and relaxed, appearing outwardly happier with more smiling. Unfortunately his night-time setting routine was upset while on treatment. The staff rated this as deterioration in his behaviour.

Patient GP was more relaxed and calm; certainly less agitated while on treatment. This had the effect of making him increasingly sleepy during the day. Both these effects were out of the normal range of behaviour for him.

Patient EN became more flexible in her verbal usage and thought content with greater social imagination and less rigidity.

Patient ME had the most dramatic response to *Secretin* of all the patients in the study. Normally his speech consists of rigid structure and poor content, speaking in single words and no sentences. During treatment he was more communicative with more spontaneous speech, occasional complete sentences, humour and laughter. He recounted tales about his fellow residents. He appeared more accepting and less troubled by responses from the staff, indicating less rigid thinking. Pre-treatment he had a fixed routine and strict structure which prevented him from forgetting things. During treatment he became forgetful of certain objects which the staff believed to be totally out of character. Unfortunately this had a negative effect, as it would lead to much frustration and agitation as a result of his forgetfulness, which the staff had to contend with. When the *Secretin* was withdrawn the staff noticed a return to his pre-treatment state within a week.

These responses were unexpected, unexplained by outside factors and never previously observed in the patients. The staff had the benefit of working with their patients over a long period of time, on average at

least 6 months. Their views and knowledge of their patients should be considered a pre-treatment behaviour base-line, on which a treatment change could be compared.

Having observed these changes, there was disappointment that the scoring did not support these observations. Possible explanations and reasons for the disappointing results are many fold. These are listed as follows:

- The CARS check list proved to be inappropriate for the patients in the study. CARS was developed for diagnosis and not for evaluating treatment outcomes. The staff found that many of the questions were aimed at children, irrelevant to their patients and too wide reaching in the responses expected. Perhaps a more specific symptom checklist including such factors as eye contact, speech, sleep, communication would have been more helpful. One such system which measures effectiveness of treatment, the Autism Treatment Evaluation Checklist, would be more appropriate for measuring those parameters mentioned earlier.
- The run-in period pre-treatment should have been longer because autistic patient’s behaviour can be so fluctuant. Acute phases of autistic behaviour can occur in this group of patients and may last from hours to days. If one of the two pre-treatment assessments had been undertaken during one of these acute phases the baseline pre-treatment mean value would be skewed by this reading. In future studies I would consider weekly pre-treatment assessments for this particular group of patients over a longer period such as 4 weeks.
- Inconsistency of assessors. Unfortunately the individual patient could not be assessed by the same pair of assessors throughout the study due to holiday/study leave and other unavoidable absences from work.
- Numbers of patients in the pilot study were too few when the variety of impairments and severity of the autistic spectrum presentations are taken into account.
- Homeopathic pharmacotherapeutic factors may be relevant. Perhaps the potency was too low. A higher

potency such as 12c or 30c should be considered in future studies. The 6c potency was chosen for reasons of caution to avoid possible aggravations.

- Because of the possibility of aggravation a ‘run-out’ phase of post-treatment observation should be included in future studies, to assess whether patients improved afterwards.
- Treatment might have been more successful with constitutional or totality prescriptions in conjunction with *Secretin*.

The outcome of this pilot study was statistically disappointing but anecdotally interesting. There were obvious changes noted in a number of the autistic patients by the care workers while treated with *Secretin*. These changes would justify further studies on *Secretin* to establish its effects, optimum potency and the patients in which it is most beneficial. I would consider undertaking a randomised controlled trial in which *Secretin* is compared with placebo. This would demonstrate that changes had occurred as a result of the medicine rather than some extraneous factor. It would also exclude subjective assessor bias in scoring the patients behaviour with the assessment tool.

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