Clinical Investigation of Bio-Chelat™

This investigation was done according to the recommendation of 83/571 EWG, Part IV, dated 11/28/1983 (EG#L332).
Planning, methodology, completion, evaluation and documentation went according to the appropriate principles for clinical drug testing, dated 12/09/1987 (Banz. Page 16-617).

Clinic-Pharmacological Data

1. **Pharmacological Dynamics**
   For this clinical evaluation, a standard dose of 3x20 drops was used and well tolerated by most patients. We recommend taking the solution before meals. With associated dryness of the mouth, follow the solution with water. We also recommended decreasing the dosage to 3x15 or a minimum of 3x10 or 2x15 drops per day when a decrease of saliva was noted. Dryness of the mouth was rarely experienced with the reduced dose and whenever it was an issue, most symptoms disappeared 3-4 weeks after taking the Bio-Chelat™.
   There was an obvious connection between the release of mercury ions from amalgam fillings by Bio-Chelat™, and the subsequent depressive effect of this release on the salivary glands. It turns out that the amount of liquid taken by the participant is of particular importance. Participants were instructed to drink a minimum of 2 liters of water per day to ensure adequate mercury excretion by the kidneys. However, not all participants followed the recommendation. Those participants, who drank less increasingly, complained of mouth dryness
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   The time-relationship-effect concludes that Bio-Chelat™ is fast absorbed and its' maximum effect occurs during the first 1-3 hours when the most excretion takes place. Because of this, it is necessary and indicated to take the solution 3 times per day. The increased digestibility after a few weeks concludes that either a tolerance occurs or that the mercury elimination is sufficiently advanced.

   To see the effect on the body, blood panels must be assessed (especially calcium, magnesium, zinc as well as heavy metals), to check for toxic consequences within the kidneys and to determine mercury excretion. Also, liver panels to determine metabolic performance and evaluate possible hepatotoxic action of Bio-Chelat™. According to the published data, there were no negative responses when observing blood count; life essential mineral concentration also did not change. Only zinc was significantly decreased, and therefore, zinc supplementation should be considered whenever necessary. Thrombocyte count also decreased slightly, while leucocytes increased minimally. On the other hand, mercury levels decreased, as well as other heavy metal ions (lead, cadmium), which is seen as a positive finding.

   Specific kidney parameters showed no negative consequences to the kidneys. In regards to the liver panel, we recognized a small insignificant increase of gamma-GT-values. The observed changes in LDH and GOT are not significant. This is most likely because of the increased demand placed on this organ with the excretion of toxic metal ions.

2. **Pharmacokinetics and Bio-availability**
   A pharmacological determination of absorption, distribution, change, and excretion of Bio-Chelat™ or its by-products did not occur. This is unusual with homeopathic diluted agents. The optimum dose is a compromise between desired effect on one hand and side effects on the other. Here it was a minimal dose of 3x10 drops and an optimal dose of 3x20 drops. The maximal dose should not be strived for.

3. **Effect with continued use**
   The therapeutic goal of mercury elimination can't be achieved in a short time because mercury is either deposited or bound to various organs. A fast mobilization by chelators can bring considerable side effects.

   Because of this it is normal and appropriate to take Bio-Chelat™ over at least a 3-month time span. Longer time periods are only indicated when, for example, there are mercury extractions, removal of amalgam fillings or new fillings are being placed.

   We know that Bio-Chelat™ is an excellent solution as long as the mercury concentration in the serum, urine or sputum continues to be high, and there are occasionally new chemical exposures that would make it useful to continue taking the solution daily.

4. **Side effects**
   None are known. In this study, no patient gave such an indication, although it should be mentioned that all participants had a naturopathic medical orientation and do not take pharmaceuticals.

Clinical Therapeutic Data

The results of this study was based on 74 participants and was documented statistically, including side effects. Each patient was questioned about side effects during the exit interview. Questions centered on how the solution was taken, as well as how they felt during the trial and how they tolerated the solution. This information is given whenever known.

- All users were clients from the HG Homeopathic Clinic, which is the practices of Drs. Pieper/Bender, Hautzel, Rebien and Schneider, as well as from the dental practices of Drs. Obermayer and Obreschko.
- Testing Method: More than 60 participants were examined, all having mercury-amalgam-fillings; their mercury and heavy metal load was checked and the effects of the Bio-Chelat™ on this heavy metal burden.
- Hypothesis: Will Bio-Chelat™ reduce this load significantly after taking it for 3 months? For verification and documentation, blood, urine, and sputum examination was used, as demonstrated on the enclosed table. Absorption spectrometry, done at the Diagnostic Center for Mineral Analysis and Spectroscopy (Lowensteinst. 9, Michelrieth), was the specific method used to measure these metals within the serum.
- The company Hormonology produced Bio-Chelat™ (a liquid solution enriched with minerals in addition to 100 ml of oxygen). The standard dose recommended by the manufacturing company was 3 x 20 drops/day. It was recommended to take a teaspoon of Bio-Chelat™ before meals, followed with water. The dose was modified when necessary for the participant.

- The test was done over a 3-month period. Because it took 3 months to find appropriate test participants, the complete study lasted from January 1, 1995 until July 31, 1995.
- No additional therapies were done or recommended.
- The desired effect was a decrease of the serum mercury, lead, cadmium, and palladium concentrations upon completion of the program.
- Undesirable effects were any associated dryness of the mouth, stomach problems and occasional nausea. These were present in a few cases and Bio-Chelat™ was discontinued. Those problems generally decreased after 3-4 weeks. Nevertheless, in a few cases an adjustment of the dosage was necessary. Side effects were generally only noted for 1-2 hours and did not cause any further problems.
- The therapeutic value of the Bio-Chelat™ in the context of other chelators that are currently on the market is seen as follows:
  Chelators work relatively fast, but they are also very strong with a relative high washout of important trace elements and a high degree of specific side effects.
  Bio-Chelat™ works much gentler than most common chelators. Although during the treatment a significant decrease of the body's heavy metal ion load was seen, this is accomplished without greatly disturbing the mineral and trace element relationships. The reduction of zinc should be looked at with caution and may easily be corrected throughout the treatment.

  A small increase in the liver panel is, as mentioned earlier, partly due to the increased load on the liver while eliminating heavy metal ions. In a few isolated cases, it was observed that those values completely approached normal levels within a few days or weeks, particularly when liver supportive and excreting therapies were simultaneously administered. All liver panel values were normal upon completion of the Bio-Chelat™ study.

  Should a patient have liver damage, and have for example an increased transaminase value, Bio-Chelat™ should be given very carefully while evaluating the risks.

  Bio-Chelat™ is not suitable for acute mercury poisoning or very high new toxic ion loads.
  Bio-Chelat™ has its greatest value as a middle and long-term therapy for sub-acute or chronic mercury toxicity. For this it is the optimal product.

  The side effects of Bio-Chelat™ are minimal when compared to the overall effect. Those side effects can be totally eliminated through a modification of intake and dose. No associated risks are connected with the use of Bio-Chelat™. After discontinuance of the Bio-Chelat™, any effects disappear within hours.

  Because of this, Bio-Chelat™ is an excellent therapy that will fill today's market niche, in view of the numerous patients carrying a chronic toxic mercury and heavy metal ion load. It is a necessary solution for that particular market.