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## **Cover sheet**

### **Title**

Interventions for atopic dermatitis in dogs

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### **Contribution of reviewers**

The following contributions will be made by the reviewers as follows:

Link with editorial base and coordinate contributions from co-reviewers (TO)

Draft protocol (TO with contributions from all)

Run search (TO, RSM, APF)

Identify relevant titles and abstracts from searches i.e. broad screen (TO, RSM, APF)

Obtain copies of trials (TO, RSM, APF)

Select which trials to include (TO, RSM, APF and HCW as arbitrator when necessary)

Extract data from trials (RSM, APF)  
Enter data into RevMan (TO)  
Carry out analysis (TO, HCW)  
Interpret analysis (TO, HCW)  
Draft final review (TO with contribution from all)  
Update review (TO)

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### **Potential conflict of interest**

Thierry Olivry performs NC State University-approved consulting activities for Novartis Animal Health Switzerland and USA (distributors of cyclosporine, which is reviewed herein). He also has a consulting agreement with Corixa, a company which does not market medications for animal use. A conflict-of-interest report is on file at this University. He has obtained recent research funding from Corixa, Heska, Novartis Animal Health, Oligos, Searle (distributors of misoprostol discussed herein), Schering-Plough Animal Health and Virbac (distributors of Genesis triamcinolone spray mentioned herein).

Ralf Mueller consults for Novartis Animal Health Switzerland and has obtained research funding from DVM Pharmaceuticals.

Chris Chesney consults for Schering-Plough and Pfizer Animal Health United Kingdom.

Neal McEwan has obtained research funding from Leo, and he participates in a trial funded by Phytopharm.

Aiden Foster has acted in the past as a consultant to Merial Animal Health UK, Leo Animal Health UK and Pfizer Animal Health UK; for Novartis Animal Health Inc and Phytopharm plc who manufacture cyclosporin and PO7P respectively. He has obtained research funding from Merial, Novartis and the Heska Corporation.

Hywel Williams does not have any conflicts of interest.

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## Background

### Definition

Atopic dermatitis (AD) is an itchy chronic skin disease that can affect humans and animals such as dogs. A task force recently defined canine AD as "a genetically-predisposed inflammatory and pruritic allergic skin disease with characteristic clinical features that is associated most commonly with IgE antibodies to environmental allergens" (Olivry 2001a).

The principal sign of canine AD is itching (pruritus), which is manifested by excessive scratching, rubbing, chewing or biting. Redness (erythema) can be observed as the earliest skin sign, but most lesions will usually result from chronic inflammation and self-trauma and therefore consist of excoriations (scratch marks), hyperpigmentation (increased pigmentation), lichenification (skin thickening) and self-induced alopecia (hair loss). Such lesions are seen most often at specific body sites, such as areas of friction and flexure, and folds on the ventral aspect (underside) of the body, face and feet (Griffin 2001a).

Investigators have used a wide array of unvalidated scoring systems to assess the severity of skin lesions of canine AD during clinical trials. These usually encompass the grading of several lesions and/or signs (e.g. pruritus) at several body sites. In 1997, Olivry and colleagues developed the first version of the Canine Atopic Dermatitis Extent and Severity Index (CADESI) (Olivry 1997). The same authors later proposed an expanded second version of the CADESI with some partial validation of intra-observer reliability (Olivry 2002). This second version of the CADESI has now been employed, sometimes in modified form, in several clinical trials in Europe, the USA and Japan. The International Task Force on Canine Atopic Dermatitis further redefined the CADESI (CADESI-03), and this revised version has been validated for validity (content, construct and criterion) and inter- and intra-observer reliability as recommended by Charman and Williams (Charman 2000).

### Prevalence and causes

The prevalence of canine AD is not known with precision, but this allergic skin disease has been shown to affect nine per cent of dogs seen by veterinarians in 52 private general practices in the USA (Lund 1999) and eight per cent of dogs admitted to 17 American veterinary teaching hospitals (Sischo 1989). In Japan, the prevalence of AD was estimated at nine per cent of dogs seen in a referral dermatology clinic (Nagata 1999). In a university veterinary hospital in the United Kingdom, AD was the diagnosis given to 43% of canine patients referred to the dermatology service (McEwan 2002).

Skin lesions of AD in dogs are sometimes, but not always, associated with signs suggestive of rhinitis and conjunctivitis (reviewed in Griffin 2001a).

The causes of canine AD are not known with certainty. Genetic factors are suspected to be important in predisposing dogs of various breeds to develop the disease (Sousa 2001a). However, breeds predisposed to AD have varied over time and geographical locations (Griffin 2001a). A young age of onset also supports the importance of a genetic influence (Griffin 2001a). At this time, it is hypothesised that, in most dogs with AD, skin lesions arise from IgE-mediated activation of immune cells after contact with allergens from the environment (Hill 2001a; Hill 2001b). Offending allergens are derived from house dust mites, pollens, moulds, insects, foods and possibly skin-surface microbes (DeBoer 2001a; Hill 2001a; Hillier 2001; Sousa 2001b). Cutaneous infections with *Staphylococcus intermedius* and/or *Malassezia pachydermatis* occur commonly, and these infections are believed to worsen the severity of clinical signs and the treatment outcome of canine AD (DeBoer 2001a).

## Treatment

The treatment of canine AD usually involves the concurrent use of multiple interventions aimed at different targets (Olivry 2001b). Whenever possible, measures to avoid allergens are implemented, especially when signs of AD worsen after ingestion of offending food allergens or after insect bites (Olivry 2001b). When offending environmental allergens are identified, allergen-specific immunotherapy can be suggested to prevent relapses of canine AD on future allergen exposure (Griffin 2001b). To reduce the severity of clinical signs, veterinary practitioners have prescribed various drugs with anti-inflammatory or antipruritic effect (Olivry 2001b). Antibacterial or antifungal medications are helpful when concurrent skin infections are diagnosed, or when microbial allergens are suspected to be involved in the perpetuation of canine AD (Olivry 2001b).

## Rationale for undertaking this review

Numerous drugs are prescribed currently to relieve signs of canine AD, and these recommendations are based on results of clinical trials performed with small numbers of canine participants or without stringent design. Moreover, many drugs are widely used without ever having been tested in any trial. There are concerns that some drugs could exhibit minimal or no beneficial effects. Additionally, medications could be shown to be effective for short-term treatment, yet could provide insufficient benefit for long-term management of canine AD. Finally, drug administration could result in harmful adverse events that are unreasonable when compared to the benefit provided. The issue of benefit must also be weighed against the cost of medication, as in many countries treatment of pet illness is not covered by veterinary medical insurance.

In the past two decades, the drugs most commonly prescribed for treatment of canine AD include glucocorticoids (Olivry 2001c), antihistamines (DeBoer 2001b), essential fatty acids (Olivry 2001d) and various nonsteroidal anti-inflammatory drugs (Marsella 2001). A systematic review was recently performed to examine the evidence of benefit and harm of pharmacological interventions used for treatment of canine AD (Olivry 2003). In this paper, a systematic review of trials using fatty acid and immunotherapy was not performed. Moreover, this paper exhibited several limitations as it included trials with or without participant randomisation, and authors did not examine clinical studies that had not been published in peer-reviewed journals. The process of participant randomisation is important to prevent the phenomenon of selection bias (Juni 2001). Because clinical trials whose results do not support the efficacy of an intervention often are not published (Oxman 2002), it is possible that this recent systematic review might have overestimated the treatment effect of some drug classes by not reviewing trials presented at meetings but not published in peer-reviewed journals. To overcome the caveats of the previous publication, it was decided to refine the process of systematic review by applying the stringent criteria established by The Cochrane Collaboration. Additionally, this collaboration provides means for regular updates of systematic reviews, hence permitting veterinarians, veterinary dermatologists and pet owners to review up-to-date information on the efficacy of interventions used for treatment of canine AD.

## Objectives

To assess the benefits and harms of interventions for the prevention or treatment of canine AD.

## Criteria for considering studies for this review

### Types of studies

This review will be limited to randomised controlled trials published in the medical or veterinary medical literature, or presented at veterinary dermatology meetings. It will include studies with either parallel or crossover designs and with or without investigator or owner masking.

### **Types of participants**

We will include all studies that enrolled dogs with skin lesions or pruritus diagnosed as AD, 'allergic inhalant dermatitis' or 'atopy'. Diagnosis by fulfilment of published diagnostic criteria such as those of [Willemse 1986](#) or [Prelaud 1998](#) will be acceptable. In the absence of specific mention of these named criteria, trials will be included if the description of the participants' clinical signs suggests the diagnosis of AD based on standard methods ([DeBoer 2001c](#); [Griffin 2001a](#)).

### **Types of interventions**

Clinical trials reporting the efficacy of the following interventions will be considered for review:

- topical or systemic pharmacological interventions
- individually administered or diet included fatty acid supplements
- injectable immunomodulators (i.e. allergen-specific immunotherapy)
- allergen-avoidance measures (i.e. house dust mite control)
- other hygiene and nutritional interventions (i.e. flea control, diet change, bathing regimens etc)

The comparator controls could be either placebo (e.g. vehicle) or another compound, known or suspected to be effective for treatment of canine AD.

### **Types of outcome measures**

Because the principal signs of canine AD consist of itching (pruritus) and skin lesions, included studies will have to report an assessment of the extent and/or intensity of these signs after a preventive or therapeutic intervention.

#### ***(1) Primary outcome measure***

The proportion of canine participants with at least a good-to-excellent improvement when evaluated on a 5-point global assessment scale (e.g. score of 4 or 5) by either investigators or dog owners.

#### ***(2) Secondary outcome measures***

- (a) The percentage of dogs with either complete remission of signs, defined by a reduction of 90% or more from baseline lesional or pruritus scores.
- (b) The percentage of dogs with a 50% or more reduction from baseline lesional and pruritus scores.

In the absence of universally accepted validated scores for evaluating skin and pruritus in dogs with AD, the outcome measures listed above will be determined from published/unpublished data derived from any scoring system used by the study authors. If none of these outcome measures can be calculated from published information, or when data cannot be obtained from the authors, then additional measures of treatment effect will be extracted directly from the papers.

## **Search strategy for identification of studies**

### **(1) Electronic databases**

Relevant trials will be identified from three databases: MEDLINE (from 1966), ISI's (Thomson) Science Citation Index Expanded (from 1945) and CAB Abstracts (from 1975).

**Search strategy for MEDLINE (OVID)***(i) Search strategy to locate RCTs*

We will modify the search terms 1-29 as given in the Cochrane Reviewers' Handbook ([Alderson 2004](#)), appendix 5b.2, to search for trials relating to dogs and not to humans.

- 1 RANDOMISED CONTROLLED TRIAL.pt.
- 2 CONTROLLED CLINICAL TRIAL.pt.
- 3 RANDOMISED CONTROLLED TRIALS.sh.
- 4 RANDOM ALLOCATION.sh.
- 5 DOUBLE BLIND METHOD.sh.
- 6 SINGLE-BLIND METHOD.sh.
- 7 or/1-6
- 8 CLINICAL TRIAL.pt.
- 9 exp CLINICAL TRIALS/
- 10 (clin\$ adj25 trial\$.ti,ab.
- 11 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
- 12 PLACEBOS.sh.
- 13 placebo\$.ti,ab.
- 14 random\$.ti,ab.
- 15 RESEARCH DESIGN.sh.
- 16 or/8-15
- 17 COMPARATIVE STUDY.sh.
- 18 exp EVALUATION STUDIES/
- 19 FOLLOW UP STUDIES.sh.
- 20 PROSPECTIVE STUDIES.sh.
- 21 (control\$ or prospectiv\$ or volunteer\$).ti,ab.
- 22 or/17-21
- 23 7 or 16 or 22
- 24 (dog\$ or canine\$.mp.
- 25 23 and 24
- 26 (human\$ or child\$.mp.
- 27 26 and 23
- 28 Animal/
- 29 28 and 23
- 30 25 not 29
- 31 25 not 27
- 32 30 or 31

*(ii) Search strategy to locate atopic dermatitis*

- 33 exp Dermatitis, Atopic/
- 34 dermatitis, atopic.mp.
- 35 eczema, atopic.mp.
- 36 atopic eczema.mp.
- 37 atopic dermatitis.mp.
- 38 atopy.mp.
- 39 allergic inhalant dermatitis.mp.
- 40 prurit\$.mp.
- 41 allerg\$.mp.
- 42 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 42

The search strategies for RCTs and disease terms will be combined

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43 32 and 42

The above is a draft search strategy that will be amended to include additional search terms where necessary. A similar strategy will be adapted for use with the other databases listed.

**(2) References from published studies**

References in the bibliographies of all clinical trials will be checked for further trials.

**(3) Unpublished literature**

Unpublished and ongoing trials will be identified by posting messages in the veterinary dermatology e-mail lists VETDERM, DIPECVD and DIPDERM.

**(4) Conference proceedings**

Proceedings booklets from the annual meetings of the American Academy of Veterinary Dermatology & American College of Veterinary Dermatology (now North American Veterinary Dermatology Forum), European Society of Veterinary Dermatology & European College of Veterinary Dermatology as well as the five World Congresses of Veterinary Dermatology will be hand searched for relevant citations. Contacts will be made to obtain information on trials presented at the meetings of the Belgian, British, French, German, Italian, Spanish, Swedish and Asian Veterinary Dermatology Associations.

**(5) Adverse effects**

Using the databases described above, additional queries will be performed as needed to search for adverse effects related to interventions described in included trials. Such searches will be done in the target species (e.g. canine), for each pharmacological intervention, and for doses, dosages and duration of treatment similar to those employed in the selected clinical trials.

**(6) Language**

There will be no language restrictions when searching for publications.

## **Methods of the review**

**(1) Study selection**

Titles and abstracts identified from searches will be examined by two reviewers (RSM and APF). If the information provided in the title and abstract suggest that the trial is not an RCT including dogs with AD, then the study will be excluded. If the information is not clear, then the full text of the paper/ presentation will be scrutinised. Any disagreement will be resolved by discussion between the reviewers, with a third reviewer (HCW) acting as arbitrator whenever needed. Excluded trials and reasons for exclusion will be recorded.

**(2) Data extraction**

This step will be achieved by two reviewers (RSM, APF) who will independently enter the information onto a data extraction form. Discrepancies will be resolved by a third reviewer (HCW). Missing data will be obtained from authors whenever possible. Data will be verified and entered into RevMan by the leading reviewer (TO). The reviewers will not be blinded to the names of authors, journal or institutions.

**(3) Assessment of methodological quality**

Quality assessment of trial designs will be performed similarly to the recent systematic review (Olivry 2003) and the following issues will be examined and rated as none', 'adequate', 'unclear' or

'inadequate'.

- (a) method of generation of randomisation sequences
- (b) method of concealment of allocation to treatment groups
- (c) masking of allocation for observers (e.g. clinicians) and participants (e.g. dog owners)
- (d) loss-to-follow-up by either dropout or withdrawal
- (e) performance of intention-to-treat analyses
- (f) quality of enrolment of study participants (e.g. characterisation of diagnosis of AD in included canine participants)

To further compare the quality of included trials, additional parameters may be recorded. Such parameters could include any available data on validation of scoring systems used, information on the co-administration of other drugs (topical or systemic), and whether the severity of baseline signs (pruritus, lesions) was adequately reported.

All data will be recorded in tabular form, and a description of the quality of each trial will be given based on the global analysis of all components.

#### **(4) Analysis**

Pooling of results and meta-analyses will be performed for studies reporting similar interventions and outcome measures, using the RevMan analysis software, by two of the reviewers (TO, HCW). Analysis of dichotomous outcomes will be reported as odds ratio (OR) with 95% confidence intervals (CI). For continuous outcomes, weighted mean difference (WMD) and 95% CI will be assessed.

We anticipate finding clinical heterogeneity between studies that assessed similar interventions because of the variable inclusion criteria for study participants (e.g. 'well-characterised' AD or presumed 'allergy', or the restriction of participants with a more or less severe phenotype). Therefore we will use a random effects model to pool the results from related studies. If moderate levels of heterogeneity are detected ( $I^2 > 50\%$ ) the reasons will be explored using sensitivity analysis (e.g. excluding studies in which the diagnosis of atopic dermatitis is less certain) and subgroup analysis (e.g. of dogs with a severe phenotype). If statistical heterogeneity is found that was not anticipated on clinical grounds beforehand, this will be explored further by going back to the original studies to determine whether there are any circumstances relating to the trial participants, intervention trial design or setting that could account for such statistical heterogeneity. We shall also perform sensitivity analyses excluding those studies judged as poor (i.e. those with inadequate or missing information on concealment of allocation, method of randomisations, blinding and intention-to-treat analysis).

Whenever possible, outcome measures will be compared between subgroups of study participants affected with AD and those with the diagnosis of 'presumed AD' or 'pruritus of allergic origin'.

Short-term treatment will refer to studies lasting less than six weeks, and long-term effect will refer to trials of more than six week duration. This separation corresponds to the time frame by which drug dosages of anti-inflammatory drugs are reduced to avoid adverse events. Where possible, data for short-term and long-term treatment with an intervention will be analysed separately.

Clinical trials lacking randomisation and control will be listed separately, but they will not be reviewed in detail. Trials reporting adverse drug events will be described in a separate section.

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## **Other references**

### **Additional references**

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