

# Adis Clinical Trials Insight

## FILE DESCRIPTION

**Adis Clinical Trials Insight** presents highly structured records of key papers, published in more than 1,300 international medical and biomedical journals, papers presented at 100 meetings and clinical data from media releases and relevant company and trial registry Web sites on drugs, drug therapy, adverse drug reactions, and pharmacoeconomics. Document types include Best Evidence, Supporting Evidence, and Ongoing Trial records.

Summaries are presented in a highly structured and consistent format to provide a clear definition of the study and results. Drug regimens, results and side effects, etc., are presented in easy-to-read tables. **Adis Clinical Trials Insight** also provides an evaluation score for clinical trials (applicable to Best Evidence records only) as an independent guide to the quality of the trial, design, and reporting.

Files 173 & 973 include all record types. Files 373 & 873 include the former Summary and Citation records. Files 873 and 973 are subscriber files.

## SUBJECT COVERAGE

- Affective Disorders
- Alzheimer's & Cognition Disorders
- Antibacterials
- Antithrombotics
- Antivirals
- Anxiety Disorders
- Arrhythmias
- Cancer Chemotherapy
- Diabetes
- Epilepsy and Seizure Disorders
- Heart Failure
- Hyperlipidaemia
- Hypertension
- Irritable Bowel Syndrome
- Ischaemic Heart Disease
- Men's Health
- Nausea & Migraine
- Neurological Disorders
- Obesity
- Obstructive Airways Disease
- Pain Control
- Parkinson's Disease
- Peptic Ulcer Disease
- Pharmacoeconomics
- Psychotic Disorders
- Rheumatic Disease
- Transplant Rejection
- Vaccines
- Women's Health

## DIALOG FILE DATA

Inclusive Dates: 1990-present (File 173)  
 1982-1989 (Files 373,873)  
 1990-present (File 973)  
 Update Frequency: Closed (Files 373,873)  
 Weekly (Files 173,973)  
 File Size:  
 More than 536,000 records as of December 2009 (File 173)  
 38,791 records (File 373)

## TIPS

### USE FILE 173

to search for information on drugs, drug therapy, adverse drug reactions, and pharmacoeconomics.

### USE AC= and CC=

to create a set of records by WHO or EphMRA category  
 SELECT AC=L01A

### SELECT UD=YYYYMMDD

to create a set of New, Significantly Modified, and Modified records in a given update

### USE DT=ONGOING TRIAL

to isolate records that profile a trial

### USE ST=

to see the various Study Status options of Ongoing Trial records

EXPAND ST=

### USE SK=

to search Endpoints and biomarkers  
 SELECT SK=BIOMARK?

### MAP LK in File 107

to find related records  
 SELECT LK=019461;MAP LK;B107;EXS

## CONTACT

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## SAMPLE RECORD

DIALOG(R)File 173:Adis Clinical Trials Insight  
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**AA=** 0000104589 801040717  
**/TI** ADIS TITLE:  
Methotrexate: therapeutic use; Rheumatoid arthritis; In patients with undifferentiated arthritis: PROMPT study

**/TI** ORIGINAL TITLE:  
Probable rheumatoid arthritis methotrexate versus placebo therapy (PROMPT)-study: indications for a window of opportunity in the treatment of patients with undifferentiated arthritis.

**CD=** ADIS CREATION DATE: 7 July 2006 (20060707)  
**PD=,PY=** PUBLICATION DATE: 1 July 2006 ( 20060701 )  
**AU=** AUTHOR(S):  
Van Dongen H; Van Aken J; Lard LR; Ronday HK; Speyer I; Westedt ML; Allaart CF; Toes REM; Breedveld FC; Huizinga TWJ

**CS=** CORPORATE SOURCE:  
Leiden University Medical Center, Leiden, The Netherlands

**JN=,SN=,SO=** JOURNAL NAME:  
Annals of the Rheumatic Diseases (Ann-Rheum-Dis) 0003-4967 65 (Suppl. II): 54 (plus oral presentation) abstr. OP0001, Jul 2006

**AS=** THERAPEUTIC AREA:  
Rheumatic Disease

**DT=** DOCUMENT TYPE: Best Evidence  
**LA=** LANGUAGE: English  
**MT=** MEETING NAME:  
Annual European Congress of Rheumatology (2006 : June 2006 : Amsterdam, Netherlands)

**NS=** STUDY NAME:  
- Probable RA: Methotrexate vs Placebo Therapy (PROMPT)

**CI=** CLINICAL RELEVANCE:  
A

**/EV,OT=** OUTCOME:  
Efficacy: Methotrexate > Placebo

**/EV,SM=** STUDY MESSAGES:  
Efficacy: Methotrexate is beneficial in patients with undifferentiated arthritis fulfilling the criteria for probable rheumatoid arthritis.

**/EV,RH=** RESULTS HIGHLIGHTS:  
Efficacy: Methotrexate was beneficial in patients with undifferentiated arthritis fulfilling the criteria for probable rheumatoid arthritis. Rheumatoid arthritis was diagnosed in 20% of methotrexate recipients compared with 29% in the placebo group. In patients with erosive disease, the rate of radiographic progression was significantly lower (<0.05).

**/EV,AE=** ADIS ASSESSMENT:  
Adis Comment: Methotrexate, an antimetabolite agent, is well established in the treatment of malignancies and autoimmune diseases such as rheumatoid arthritis. It acts specifically by inhibiting folic acid metabolism. In rheumatoid arthritis, the action of methotrexate appears to involve interference in immune function which may play a role in the pathogenesis of the disease. Professor Tom Huizinga, one of the study investigators, comments that the PROMPT data are "excellent news" as they show "that methotrexate appears to delay or even prevent progression to rheumatoid arthritis." Another PROMPT investigator, Henrike Van Dongen, says that "one of the most interesting findings from the study was that the patients who benefited the most were the ones showing a positive anti-CCP test, which would in general terms show that a patient has a very high likelihood of developing full-blown rheumatoid arthritis; however, this study indicates that the progression to a full-blown disease amongst these patients could be influenced." This study was published as an abstract in the proceedings of the 2006 Annual European Congress of Rheumatology (EULAR) held in Amsterdam, The Netherlands, in June 2006. Additional information used in this assessment was presented orally at the conference.

**/TX** STUDY PURPOSE:  
This study investigated the benefits of methotrexate treatment in patients with undifferentiated arthritis fulfilling the 1958 American College of Rheumatology (ACR) criteria for probable rheumatoid arthritis. The primary endpoints were the rates of rheumatoid arthritis (according to the 1987 ACR criteria) and radiographic progression (according to the Sharp/van der Heijde scores).

**/TX** AUTHOR COMMENT:  
"Patients with UA (undifferentiated arthritis) fulfilling the ACR 1958

**SAMPLE RECORD (cont'd)**

criteria for probable RA (rheumatoid arthritis) benefit from treatment with MTX (methotrexate). Fewer patients fulfil the ACR 1987 criteria for RA and they do so at a later time point. MTX treatment also resulted in less progression in radiographic joint damage. Anti-CCP (citrullinated peptide)-positive patients seem to benefit most from treatment with MTX, which indicates the existence of a window of opportunity in anti-CCP-positive arthritic patients to influence the disease progression into full-blown RA. This is the first RCT (randomised controlled trial) that demonstrates the existence of such a window of opportunity."

**/TX**

**STUDY DETAILS:**

**SI=**

Design: double-blind, multicentre, randomised  
Control: placebo comparison, baseline comparison

**PS=**

Phase: III

**SK=**

Endpoints: Kaplan-Meier-survival-rate, Disease-progression-rate, Radiographic-outcomes, Remission-rate, American-College-of-Rheumatology-criteria, Time-to-disease-occurrence  
Name: Probable RA: Methotrexate vs Placebo Therapy (PROMPT)

**SUBJECT DETAILS:**

Type: patients  
No: 110  
Age: mean 51 years  
Sex: not stated  
Location: Unknown  
Disease: Rheumatoid-arthritis  
Patient Inclusion: undifferentiated arthritis fulfilling the 1958 ACR  
<=2 years

**PK=**

Patient Age Keywords: adult

**/TX**

**TREATMENTS:**

Methotrexate

Drug/Treatment	Dose	Route	Frequency	Duration
Methotrexate	15-30 mg/week	PO	1/week	>12 months

Placebo  
Placebo

**RESULTS:**

Outcomes (% patients)	Placebo	Methotrexate
Rheumatoid arthritis Remission	29 11	20 18

**ATC CODES:**

WHO: L01BA01  
EPhMRA: L01B

**AC=**

**CC=**

**/DE, /DU, /DI**

**DESCRIPTORS:**

DRUG: Methotrexate, therapeutic use  
DISEASE: Rheumatoid arthritis, treatment

**LK=**

R&D INSIGHT LINK(S):  
020557; 021340

## SEARCH OPTIONS

## BASIC INDEX

SEARCH SUFFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
—	—	All Basic Index Fields	Word	S STAGE(W)I(W)HYPERTENSION
/CR	CR	References <sup>1,3</sup>	Word	S ELI(W)LILLY/CR
/DE	DE	Descriptor	Word & Phrase	S CANDESARTAN(W)CILEXETIL/DE
/DI	DI	Disease Descriptors	Phrase	S HYPERTENSION(L)PREVENTION/DE
/DU	DU	Drug Descriptors	Phrase & Word & Phrase	S RHEUMATOID ARTHRITIS/DI S METHOTREXATE(L)THERAPEUTIC?/DU S METHOTREXATE/DU S METHOTREXATE(L)THERAPEUTIC USE/DI
/EV	EV	Evaluation	Word	S PLACEBO(W)RECIPIENTS/EV
/NA	DG	Drug Name <sup>1,2</sup>	Phrase	S CANDESARTAN-CILEXETIL/NA
/OD	OD	Other Descriptors <sup>1</sup>	Word & Phrase	S RESEARCH(1W)DEVELOPMENT/OD S RESEARCH "AND" DEVELOP?/OD
/PR	PR	Pharmacoeconomic Descriptors	Word & Phrase	S DECISION(W)ANALYSIS/PR S MANAGED CARE/PR
/SE	SE	Side Effects <sup>4</sup>	Word	S NEUROLOGICAL/SE
/TI	TI	Adis Title and Original Title	Word	S METHOTREXATE(S)RHEUMATOID/TI
/TX	AF	Adverse Effects <sup>1</sup>	Word	S CLINICAL(W)CURE/TX
/TX	CA	Case Details <sup>4</sup>	Word	S TREATING(W)GABHS/TX
/TX	CT	Author Comment <sup>1</sup>	Word	S PATIENTS(1W)UA/TX
/TX	OC	Ongoing Trials Comment <sup>1,3</sup>	Word	S ARTHRITIS(2N)METHOTREXATE/TX
/TX	PU	Study Purpose <sup>1</sup>	Word	S BENEFITS(1W)METHOTREXATE/TX
/TX	RE	Results <sup>1</sup>	Word	S ARTHRITIS(1W)REMISSION/TX
/TX	SD	Study Details <sup>1</sup>	Word	S DOUBLE(W)BLIND/TX
/TX	SJ	Subject Details <sup>1</sup>	Word	S UNDIFFERENTIATED(W)ARTHRI?/TX
/TX	TR	Treatments <sup>1</sup>	Word	S METHOTREXATE/TX
/TX	TX	Text	Word	S CITRULLINATED(W)PEPTIDE/TX

<sup>1</sup> Only in Files 173 & 973.<sup>4</sup> Only in Files 373 and 873.<sup>2</sup> Use the UDF (NA or DG) or KWIC to display.<sup>3</sup> Only found in DT=ONGOING TRIAL records.

## ADDITIONAL INDEXES

SEARCH PREFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
AA=	AA	Adis Accession Number	Phrase	S AA= 801040717
AC=	AC	ATC WHO Codes <sup>1</sup>	Phrase	S AC= L01BA01
AE=	AE	Adis Assessment <sup>5</sup>	Word & Phrase	S AE=(PHARMACOLOGICAL(W) INTERVEN?) S AE=THIS STUDY WAS PRESENTED?
AS=	AS	Therapeutic Area	Phrase	S AS=RHEUMATIC DISEASE
AU=	AU	Author	Phrase	S AU=VAN DONGEN H
—	AZ	DIALOG Accession Number		
CC=	CC	EphMRA Codes <sup>1</sup>	Phrase	S CC=L01B
CD=	CD	Adis Creation Date <sup>1,6</sup>	Phrase	S CD=20060707
CI=	CI	Clinical Relevance	Phrase	S CI=A
CR=	CR	References <sup>1,3</sup>	Word	S CR=(ELI(W)LILLY)
CS=	CS	Corporate Source <sup>7</sup>	Word	S CS=(LEIDEN(W)UNIVERSITY) S CS=LEIDEN UNIVERSITY MEDICAL?
—	DG	Dose Units, Drug Route, Maximum Dose, Minimum Dose <sup>1,2</sup>		
DT=	DT	Document Type <sup>8</sup>	Phrase	S DT=BEST EVIDENCE
ES=	ES	Adis Score	Phrase	S ES=72
JN=	JN	Journal Name	Phrase	S JN=ANNALS OF THE RHEUMATIC DISEAS?
LA=	LA	Language	Phrase	S LA=ENGLISH
LK=	LK	R&D Insight Link <sup>1,12</sup>	Phrase	S LK=020557
MT=	MT	Meeting Name <sup>1</sup>	Word	S MT=(ANNUAL(W)EUROPEAN(S)RHEUMA?)
NA=	DG	Drug Name <sup>1,2</sup>	Phrase	S NA=METHOTREXATE
NG=	NG	Number of Patient Groups <sup>4</sup>	Phrase	S NG=7
NP=	NP	Number of Patients <sup>1</sup>	Phrase	S NP=110
NS=	NS	Study Name <sup>1,13</sup>	Word & Phrase	S NS=(PROBABLE(W)RA(F) METHOTREXATE) S NS=PROBABLE RA?
NT=	NT	Adis Comment	Word	S NT=(ANTIMETABOLITE(W)AGENT)
OT=	OT	Outcome <sup>5</sup>	Phrase	S OT="METHOTREXATE > PLACEBO"
PD=	PD	Publication Date	Phrase	S PD=20060701
PK=	PK	Patient Age Keywords	Phrase	S PK=ADULT
—	PM	Patient Minimum Age <sup>1</sup>		
PP=	PP	Planned Number of Patients <sup>1</sup>	Numeric	S PP=1000
PS=	PS	Study Phase	Phrase	S PS=PHASE III
—	PX	Patient Maximum Age <sup>1</sup>		
PY=	PY	Publication Year	Phrase	S PY=2006

## ADDITIONAL INDEXES (cont'd)

SEARCH PREFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
RH=	RH	Results Highlights <sup>5,9</sup>	Word	S RH=(EROSIVE(W)DISEASE)
SI=	SI	Study Design	Phrase	S SI=RANDOMISED
SK=	SK	Study Endpoints <sup>9</sup>	Phrase	S SK=KAPLAN MEIER?
SM=	SM	Study Messages <sup>5,9</sup>	Word	S SM=(METHOTREXATE(1W)BENEFICIAL)
SN=	SN	International Standard Serial Number <sup>1</sup>	Phrase	S SN=0003-4967 S SN=00034967
SO=	SO	Source Information <sup>10</sup>	Word	S SO=(RHEUMATIC AND JUL(W)2006)
ST=	ST	Study Status <sup>1</sup>	Phrase	S ST=IN PROGRESS
TL=	TL	Clinical Trials Number <sup>1,11</sup>	Phrase	S TL=ID01-604
TY=	TY	Study Controls	Phrase	S TY=PLACEBO COMPARISON
UD=	—	Update	Phrase	S UD=9999
UP=	UP	Last Update Date <sup>1,3</sup>	Phrase	S UP=20060323

<sup>5</sup> Also searchable as /EV.

<sup>6</sup> The date that the Adis record was created.

<sup>7</sup> The linking between authors and institutions is not present until October 2005.

<sup>8</sup> Files 173 & 973 include Best Evidence (beginning 1990), Supporting Evidence (beginning 2005), Ongoing Trials (beginning 2005), and Citation-only records (from 1990-2004). Beginning in 2005, Citation-only records are superseded by Supporting Evidence records. Files 373 & 873 include the former Summary and Citation records only.

<sup>9</sup> Available in records from 1996 forward.

<sup>10</sup> Search and Display include Journal Name, Volume, Issue, Pages, and Publication Date.

<sup>11</sup> MAP RRTL in File 173/973 to find related records.

<sup>12</sup> MAP LK in File 107 to find related records.

<sup>13</sup> MAP RRNS in File 173/973 to find related records.

**Files 173,373,873,973**  
**SPECIAL FEATURES**

**Adis Clinical Trials Insight**

For command descriptions, enter HELP LIMIT, HELP SORT, HELP RANK, HELP MAP, HELP DUP online.

<b>LIMIT</b>	/BEST -- Best Evidence Records /CIT -- Citation-only Records /ONGOING -- Ongoing Trials Records /SUPPORT -- Supporting Evidence Records /YYYY -- Publication Year	S S1/BEST S ANTIRHEUMATICS/CIT S S3/ONGOING S UD=?/SUPPORT S S4/2005:2006
<b>SORT</b>	AU, CS, JN, PD, PY, TI	SORT S5/ALL/PY/D SORT S1/ALL/CS
<b>RANK</b>	All phrase- and numeric-indexed fields in the Additional Indexes can be ranked. Other RANK codes include: DE	RANK CS RANK AU S4
<b>MAP</b>	LK, RRNS, RRTL	MAP LK TEMP S2
<b>RD, ID</b>	Remove duplicates (RD) or identify duplicates (ID,IDO).	RD S5

**PREDEFINED FORMAT OPTIONS**

NO.	DIALOGWEB FORMAT	RECORD CONTENT
1	--	DIALOG Accession Number
2	Short	Full Record except Text fields
3	Medium	Full Record except Text fields
4	--	Full Record Tagged
5	Long	Full Record
6	Free	Adis Accession Number, Adis Title, Original Title, Creation Date, Publication Date, Last Update Date (for Ongoing Trial records only), Document Type, Record Type, R&D Insight Link, WHO and EphMRA Codes
7	--	Full Record except indexing, i.e., /DE,(DI, /DU, /OD, /PR), AC=, CC=, TL=
8	Free	Adis Accession Number, Adis Title, Original Title, Creation Date, Publication Date, Document Type, Record Type, Last Update Date (for Ongoing Trial records only), Descriptors, WHO and EphMRA codes, R&D Insight Link, Language
9	Full	Full Record
K	--	KWIC (Key Word In Context) displays a window of text; may be used alone or with other formats

**OTHER OUTPUT OPTIONS**

For an explanation, enter HELP TYPE, HELP UDF, HELP TAG online.

<b>USER DEFINED FORMATS</b>	Display codes listed in the Search Options tables can be used to customize output.	TYPE S4/TI, EV, PY/1-5 PRINT S5/TI, AE, AS/ALL
<b>TAG</b>	Output can be displayed with tags identifying each display field.	TYPE S1/5/ALL TAG PRINT S3/9/1-5 TAG
<b>DIRECT RECORD ACCESS</b>	If the accession number of a specific record is known, it can be used to display the record directly.	TYPE 016601/9 PRINT 016009/5

**FOR ONLINE HELP:**

See HELP FIELDS 173 for searchable fields; HELP FORMAT 173 for output formats; HELP LIMIT 173 for limits; HELP RATES 173 for cost information; HELP SORT 173 for sorts.