자료추출 및 비뚤림위험 평가

1. 자료추출

연번(Ref ID)	3								
1저자(출판연도)	Bogacz	Bogacz_Piaseczynska 2022							
연구특성		연구수행국가*: Poland연구대상자 모집기간: 2022							
연구대상	- 질환! - 알레! • 환자수	 연구대상: Moderate-to severe AD a minimum of one year 질환명: 아토피피부염 알레르겐: House Dust Mites 환자수: 37(21/16) ⇒ 34 (20/14) 평균연령: 중재군 18.5 ±11.3, 대조군 20.1 ±8.3 							
중재법	• 알레르	• 알레르겐 면역요법 방법: SCIT, Subcutaneous immunotherapy							
비교중재법		Placebo cations)	Inj. (Oral	antihista	ımines,	such as	deslor	atadine	and topical
추적관찰 및	• 추적관	<u>:</u> 찰기간: 12	2개월						
결과변수		: 중재군 9							
결과분석방법	scale Derm - Statist - The n - The V - The A	 결과변수: EASI (Eczema Area and Severity Index), BSA (body surface area) scale, At least 3 points on the IsGA (investigator global assessment) scale, Dermatology Life Quality of Index (DLQI) Statistica version 8.12 (SoftPol, Cracow, Poland) The non-parametric tests: not normally distributed The Wilcoxon test: differences between the groups. The ANOVA test: to compare scale scores. Differences were considered significant when p < 0.05. 							
:				vhen p <	0.05.				
				vhen p <	0.05.	ctions, SAE	s: Seve	ere Adve	rse Events
	• SRs:	Systemic	reactions	vhen p <	0.05.	· ·	s: Seve 조군, (명)	ere Adve	р
		Systemic 시점 (개월)	reactions. 전 Events	vhen p 〈 , LRs: Lo 5재군, (명) Total	0.05.	대: Events	조군, (명) Total	ere Adve	
연구결과-안전성	• SRs:	Systemic 시점 (개월) 12	reactions, Events	vhen p 〈 , LRs: Lo 5재군, (명) Total 31	0.05. cal read	Events	조군, (명) Total 16	%	p -value -
연구결과-안전성	• SRs: 구분 SRs	Systemic 시점 (개월) 12 18	reactions, Events 1 9	vhen p 〈 , LRs: Lo 5재군, (명) Total 31 112	0.05. cal read	Events 0 20	조군, (명) Total 16 55		р
연구결과-안전성	・ SRs: 구분 SRs LRs	Systemic 시점 (개월) 12 18 12	reactions, Events 1 9 5	vhen p 〈 , LRs: Lo §재군, (智) Total 31 112 31	0.05. cal read	Events 0 20 0	조군, (명) Total 16 55 16	%	p -value -
연구결과-안전성	• SRs: 7분 SRs LRs SAEs	Systemic 시점 (개월) 12 18	reactions. Events 1 9 5 NR	vhen p 〈 , LRs: Lo , Total 31 112 31 31 31	0.05. cal reac % 8%	CH: Events 0 20 0 NR	조군, (명) Total 16 55	%	p -value -
연구결과-안전성	• SRs: 구분 SRs LRs SAEs	Systemic	reactions. Events 1 9 5 NR	vhen p 〈 , LRs: Lo FM군, (명) Total 31 112 31 31 31 Area and S	0.05. cal read % 8%	CH: Events 0 20 0 NR	조군, (명) Total 16 55 16	10.7%	p -value -
연구결과-안전성	• SRs: 7분 SRs LRs SAEs	Systemic 시점 (개월) 12 18 12 12 12 14: EASI (reactions. Events 1 9 5 NR Eczema A	vhen p 〈 , LRs: Lo , LRs: Lo , Total	0.05. cal reac % 8% Severity	Events 0 20 0 NR	조군 , (명) Total 16 55 16 16	%	p -value -
	• SRs: 구분 SRs LRs SAEs • 결과변	Systemic 시점 (개월) 12 18 12 12 12 14: EASI (Events 1 9 5 NR Eczema A 중재급 an SD dian] [IQR/ra 3 8.2	vhen p 〈 , LRs: Lo , LRs: Lo , (智)	0.05. cal reac % 8% Severity	대: Events 0 20 0 NR Index) 대조군	조군 , (명) Total 16 55 16 16	% 10.7%	p -value - - - -

결론

Funding

Funding: This research received no external funding.

- AD 환자와 단일감작 HDM 환자의 알레르기 항원 면역요법은 위약군에 비해 치료 1년 후

질병의 임상과정을 개선함. 추가 연구 필요함

연번(Ref ID)	68						
1저자(출판연도)	Sanchez Ca	raballo 2012					
연구특성	연구수행국가*: 콜롬비아연구기관:연구대상자 모집기간: 2009.9.~2010.1.						
연구대상	 연구대상: AD for more than 2 years with/without Asthma/Rhinitis 질환명: 아토피피부염 알레르겐: House Dust Mites, dog dander, pollen grains 환자수: 60(31/29) 평균연령: 중재군 8 (3~24), 대조군 8 (3~25) 						
중재법	• 알레르겐 면역	역요법 방법: SCIT,	Subcutane	ous immu	nothe	rapy	
비교중재법	tacrolimus	herapy: Oral an were admin f symptoms					
추적관찰 및 결과변수	추적관찰기간순응도: 미보	止: 6개월, 12개월 고					
	 결과변수: SRs: Systemic reactions, Scoring Atopic Dermatitis (SCORAD) Efficacy of treatment, reduction of drugs, wheal sizes, total IgE, and specific IgE and IgG4 were compared between both groups using the Mann-Whitney test. Because the effect of immunotherapy is detectable after several months of treatment, evaluation of effectiveness was performed based on protocol analysis; Proportions were analyzed using contingency tables, and the Fisher exact test was conducted. P (0.05 was considered statistically significant. For the primary outcome (clinical response), a sample size of 58 subjects would provide a statistical power of 80% to detect a mean difference of 30%. 						
결과분석방법	Mann-Whi after sever performed contingenc • P < 0.05 v • For the pr subjects w	tney test. Beca ral months of tr based on proto cy tables, and th was considered imary outcome yould provide a	use the efreatment, es secol analysine Fisher es statistically (clinical res	fect of im evaluation s; Proport exact test sponse), a	muno of eff ions v was ont.	therapy fectivene were and conducte ole size	is detectable ess was alyzed using ed.
결과분석방법	Mann-Whi after sever performed contingence • P (0.05 v • For the pr subjects w difference	tney test. Beca ral months of tr based on proto cy tables, and th was considered imary outcome yould provide a	use the efreatment, es secol analysine Fisher es statistically (clinical res	fect of im evaluation s; Proport exact test sponse), a	muno of eff ions v was ont.	therapy fectivene were and conducte ole size	is detectable ess was alyzed using ed.
	Mann-Whi after sever performed contingence • P < 0.05 v • For the pr subjects w difference • SRs: Syste	tney test. Becaral months of to based on protesty tables, and the was considered rimary outcome vould provide a of 30%.	use the effeatment, especial analysine Fisher estatistically (clinical restatistical)	fect of im evaluation s; Proport exact test sponse), a	muno of eff ions v was ont.	therapy fectiveners were and conducted ple size to detect	is detectable ess was alyzed using ed. of 58 et a mean
결과분석방법	Mann-Whi after sever performed contingence • P < 0.05 v • For the pr subjects w difference • SRs: Syste	tney test. Becaral months of the based on protect tables, and the was considered imary outcome would provide a of 30%. The second of the second of 30%. The second of the second of 30%.	use the effeatment, especial analysine Fisher estatistically (clinical restatistical)	fect of im evaluation s; Proport exact test / significar sponse), a power of t	muno of eff ions v was ont.	therapy fectivene were and conducted ple size to detect	is detectable ess was alyzed using ed.
	Mann-Whi after sever performed contingence P (0.05 v For the pr subjects w difference SRs: Syste	tney test. Becaral months of the based on protocy tables, and the was considered imary outcome would provide a of 30%. Semic reactions STATE, (9) Events Total CORAD >50: Sevents	wise the effectment, expected analysis in the Fisher estatistically (clinical restatistically) (clinic	fect of imevaluation s; Proport exact test exact test cy significar sponse), a power of start test 29 max Total 29 max Mean	muno of eff ions v was ont. or samp 80% f	therapy fectiveness were an econducted to detect to dete	is detectable ess was alyzed using ed. of 58 et a mean # 2
연구결과-안전성	Mann-Whi after sever performed contingence • P < 0.05 v • For the pr subjects w difference • SRs: Syste 결과지표 시간 양명 SRs 12	tney test. Becaral months of treat based on protocy tables, and the was considered in imary outcome would provide a of 30%. Semic reactions Servents Total CORAD >50: Sevents Servents Mean Signedian Servents Mean Signedian Servents 22.09 3.5	wise the effectment, especial analysis he Fisher estatistically (clinical restatistical position) Which is the effect of the statistical position in the statistical position is the statistical posi	fect of imevaluation s; Proport exact test in sex sponse), a power of the sex sponse), a power of the sex sponse), a power of the sex sponse in sex sponse	muno of efficients was ont. in sample 80% 1 GLORIFIANT SD [IQR/rail]	p value rongel (8	is detectable ess was alyzed using ed. of 58 et a mean 비고 p- tal y) value
연구결과-안전성	Mann-Whi after sever performed contingence • P < 0.05 % • For the pr subjects w difference • SRs: Syste 결과지표 시경 SRs 12	tney test. Becaral months of treated on protocycles, and the was considered imary outcome vould provide a of 30%. Semic reactions STATE CORAD >50: Several Mean SI [median] [log/resisted]	wise the effectment, especial analysis he Fisher estatistically (clinical restatistical position) Which is the effect of the statistical position in the statistical position is the statistical posi	fect of imevaluation s; Proport exact test in sponse, a power of the state of the	muno of efficients was on the same 80% of the same 80% of the same 80% of the same same 80% of the same same same same same same same sam	p value rongel (8	is detectable ess was alyzed using ed. of 58 et a mean # 2 p- tal value
연구결과-안전성	Mann-Whi after sever performed contingence • P < 0.05 v • For the pro- subjects w difference • SRs: Syste 결과지표 시점 SRs 12 • 결과변수: SO 결과 측정 지표 시점 SCO- RAD 12M	tney test. Becaral months of tribased on protocy tables, and the was considered imary outcome vould provide a of 30%. STATE O 31 CORAD >50: Sevents Total 2 0 31 CORAD >50: Sevents State Sta	use the efreatment, epocl analysis in Event (clinical restatistical) (fect of imevaluation s; Proport exact test can be spower of state of the second secon	muno of efficions v was onto the same with	therapy fectivener were and conducted to detect to dete	is detectable ess was alyzed using ed. of 58 that a mean blue yet value yet value yet using ed. of 58 that a mean
연구결과-안전성	Mann-Whi after sever performed contingence • P 〈 0.05 N • For the pr subjects w difference • SRs: Syste 결과지표 시경 (개월 SRs 12 • 결과변수: SCO 결과 측정 지표 시점 SCO- RAD 12M • 알레르의 유도구 • 아토피성 및 • 마당의 의 의 의 의 의 의 의 의 의 의 의 의 의 의 의 의 의 의	tney test. Becaral months of tribased on protocy tables, and the was considered imary outcome vould provide a of 30%. Imic reactions Image: Structure of 30% of	use the effectment, especial analysis he Fisher estatistically (clinical restatistically (clinical restatistical part of the statistical part of the	fect of imevaluation s; Proport exact test care test care for spower of state of the spower of state of state of the spower of state of spower of state of the spower of state of the spower of state of spower of state of spower of state of spower of state of spower of spower of state of spower	muno of efficions views ont. sam, 80% 1 sam, 80% 1 sam, 10 sa	therapy fectivener were and conducted to detect to dete	is detectable ess was alyzed using ed. of 58 et a mean H고 p- tal p- value 9 9 0.0001 격 및 IgG4 피부염 관리에

연번(Ref ID)	320				
1저자(출판연도)	Novak 2012				
연구특성	 연구수행국가*: 독일 Recruited at 21 centers in Germany 연구대상자 모집기간: 2007. 3. ~ 2009. 1. 	_			
연구대상	 연구대상: Moderate to severe AD duration 〉2 years 질환명: 아토피피부염 알레르겐: House Dust Mites 환자수: 168 (112/56) ⇒ ITT(107/55), PP(76/39) 평균연령: 18~66세 				
중재법	• 알레르겐 면역요법 방법: SCIT, Subcutaneous immunotherapy				
비교중재법	Basic medication + Placebo				
추적관찰 및 결과변수	추적관찰기간: 3개월, 6개월, 12개월, 18개월(76주)순응도: 중재군 67.8%, 대조군 69.6%				
결과분석방법	 결과변수: SRs: Systemic reactions, Scoring Atopic Dermatitis (SCORAD), DLQ (Dermatology Life Quality of Index) score, Immunonologic markers (AUC) values for both the total SCORAD and the use of basic medication (th "medication score") over the 18-month treatment period. The 1-sided of Wilcoxon rank-sum test was used for all primary analysis variables to show superiority or inferiority of the SCIT-treated group compared with the placebo-treated group. Subgroups were specified after the primary analysis in an explorator analysis. 	ne or w ne			
	SRs: Systemic reactions	_			
연구결과-안전성	시점 중재군, (명) 대조군, (명) p (개월) Events Total % Events Total % -value				
	(개월) Events Total % Events Total % -value 18 9 112 8% 20 55 10.7% -				
	• 결과변수: 증상점수 - SCORAD)50: Severe AD, Mean Diff.	_			
	중재군 대조군				
연구결과-효과성	측정 Mean SD Total Mean SD Total value [median] [IQR/range] (명) [median] [IQR/range] (명)				
	18M 24.5 11.66 107 44.8 12.56 55	_			
	-33 13.8 107 -17.5 12.5 55	_			
결론	• 진드기 추출물을 이용한 면역치료는 아토피피부염 환자 치료가 효과적이고 안전하며, 특히 HDM에 민감하게 반응하는 중증 환자의 경우, 가치있는 추가 치료법으로 간주됨	— ō			
Funding	 Supported by LETI Pharma GmbH, Germany. LETI Pharma GmbH wa involved in the design and conduct of the study and provided logistical support during the trial. Employees of the sponsor worked with the investigators to prepare the statistical analysis plan, but the analyses were performed by Pierrel Research Europe. 	S			

2. 비뚤림위험 평가

연번(Ref ID)		3
1저자(출판연도)		Bogacz_Piaseczynska 2022
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	■ 낮음 □ 높음 □ 불확실	This randomised, placebo-controlled, double-blind 12-month trial was performed in the Clinical Outpatient Allergy Department between 2021 and 2022.
Allocation concealment (배정순서 은폐)	■ 낮음 □ 높음 □ 불확실	The randomisation procedure with random selection relied on the use of computer-generated numbers by the use of a coin flip generator (Excel, 2021, Microsoft). Finally, 21 subjects received SCIT, and 16 participants formed the placebo group. The groups were comparable at baseline in most of the variables
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	■ 낮음 □ 높음 □ 불확실	Thirty-seven patients were individually randomised in comparable numbers to one of two "parallel" groups using a double-blind method (Figure 1).
Blinding of outcome assessment (결과평가에 대한 눈가림)	□ 낮음 □ 높음 ■ 불확실	언급없음
Incomplete outcome data addressed (불충분한 결과자료)	□ 낮음 □ 높음 ■ 불확실	During the 12 months of observation, the number of AD exacerbations in the study group was significantly lower compared with the placebo: 1.4 vs. 2.9 per patient during 12 months of observation for p \(\lambda \) 0.05. - SCIT (n=20), Placebo (n=14)
Free of selective reporting (선택적 보고)	■ 낮음 □ 높음 □ 불확실	 SRs: Systemic reactions, LRs: Local reactions, SAEs: Severe Adverse Events 결과변수: EASI (Eczema Area and Severity Index)
Other bias : Funding (그 외 비뚤림)	■ 낮음 □ 높음 □ 불확실	Funding: This research received no external funding.

연번(Ref ID)		68
1저자(출판연도)		Sanchez Caraballo 2012
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	□ 낮음 □ 높음 ■ 불확실	 This is an open label, controlled, randomized study. Patients were enrolled during September 2009 to January 2010. After a baseline, patients were stratified according to sensitization pattern in monoand poly-sensitized and randomized to receive immunotherapy and pharmacotherapy (active group) or only pharmacotherapy (control group).
Allocation concealment (배정순서 은폐)	□ 낮음 □ 높음 ■ 불확실	• 언급없음
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	□ 낮음 ■ 높음 □ 불확실	 This is an open label, controlled, randomized study.
Blinding of outcome assessment (결과평가에 대한 눈가림)	□ 낮음 ■ 높음 □ 불확실	 Single-Blinded Placebo-Controlled At the beginning of the study 26 patients had a self-reported adverse reaction after eating some food but in 24 of these patients the clinical history was not clear and had a negative prick test.
Incomplete outcome data addressed (불충분한 결과자료)	■ 낮음 □ 높음 □ 불확실	 Change in symptoms evaluated with objective and subjective scales at different time points. Blue: Active group. Red: Control Group. Figure 2: SCORAD: Scoring Atopic Dermatitis, VAS: Analog Visual Scale, SS: Subjective Scale. P ≤ 0.05; n = 60; Figure 3: n = 60;
Free of selective reporting (선택적 보고)	■ 낮음 □ 높음 □ 불확실	 안전성 결과변수: Systemic reactions 효과성 결과변수: Scoring Atopic Dermatitis (SCORAD) Change in Sensitization Pattern in Both Groups after One Year. After one year, change in pattern sensitization in both groups were observed (Table 2).
Other bias : Funding (그 외 비뚤림)	■ 낮음 □ 높음 □ 불확실	The authors do not have any conflict of interests to declare.

연번(Ref ID)		320
1저자(출판연도)		Novak 2012
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	■ 낮음 □ 높음 □ 불확실	 This was a randomized, double-blind, placebo-controlled, parallel group study.
Allocation concealment (배정순서 은폐)	□ 낮음 □ 높음 ■ 불확실	 randomly assigned to add-on therapy with SCIT treatment or to placebo, in addition to their basic medication, in an allocation ratio of 2:1 (Fig 1). A simple randomization procedure (computerized random numbers) was used.
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	낮음높음불확실	• 연구참여자 및 연구자에 대한 눈가림은 불확실함
Blinding of outcome assessment (결과평가에 대한 눈가림)	□ 낮음 ■ 높음 □ 불확실	 The primary efficacy end points were the total SCORAD scores and the use of basic medication (ie, cumulative application of topical medication and overall consumption of systemic medication), both over the 18-month treatment period. Secondary efficacy was provided by quality-of-life questionnaires with the use of the Dermatology Life Quality Index (DLQI), evaluated for the whole treatment period and for the heating period from September to February. Adverse reactions reported by the patient or noted by the investigator were documented during the whole study according to the European Academy of Allergy and Clinical Immunology scale
Incomplete outcome data addressed (불충분한 결과자료)	■ 낮음 □ 높음 □ 불확실	 Median improvement of the AUC of the SCORAD over 18 months was 6% in the actively treated group versus the placebo-treated group, and median improvement of the AUC of the medication score over 18 months of treatment was 32% in the actively treated group versus the placebo-treated group in the ITT set. As shown in Table III, total SCORAD was statistically significantly lower (P 5.02) for the ITT study population, with a median reduction of the AUC of the total SCORAD of 18% in the actively treated group versus the placebo-treated group. This effect was also seen in the PP study population, although it did not reach statistical significance (P 5 .03).
Free of selective reporting (선택적 보고)	□ 낮음 ■ 높음 □ 불확실	 SRs: Systemic reactions, Scoring Atopic Dermatitis (SCORAD), DLQI (Dermatology Life Quality of Index) score, Immunonologic markers Subgroups were specified after the primary analysis in an exploratory analysis.
Other bias : Funding (그 외 비뚤림)	□ 낮음 ■ 높음 □ 불확실	 Supported by LETI Pharma GmbH, Germany. LETI Pharma GmbH was involved in the design and conduct of the study and provided logistical support during the trial. Employees of the sponsor worked with the investigators to prepare the statistical analysis plan, but the analyses were performed by Pierrel Research Europe.